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

London, 10 September 2002
Doc. Ref: EMEA/22314/02

Committee for Proprietary Medicinal Products (CPMP)
Committee for Veterinary Medicinal Products (CVMP)

Position Paper

on

Re-establishment of Working Seeds and Working Cell Banks using TSE compliant materials

Background

On 28 February 2001, the CPMP issued an Explanatory Note[1] on the scope of the *CPMP/CVMP Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products* (TSE Note for Guidance)[2]. This Explanatory Note also confirms that all materials that fall within the scope of the Note for Guidance that are used in manufacturing processes, such as fermentation and in the establishment of working seeds (WSs) and working cell banks (WCBs), should be in full compliance with the TSE Note for Guidance. This proposal is in line with the CVMP's position[3].

CPMP/CVMP position on established Working seeds and Working cell banks[4]

For established WSs or WCBs which have been subjected to a properly conducted risk assessment by a competent authority and declared to be acceptable, they should be considered to be fulfilling the obligation laid down in the Annex to Directives 2001/82/EC and 2001/83/EC. Following a favourable risk assessment, they are also considered to fulfil the obligation laid down in the Annex to Directive 2001/82/EC and 2001/83/EC when such WSs or WCBs are incorporated in new marketing authorisation applications[5].

[1] Document EMEA/CPMP/BWP/498/01.
[2] Since February 2001, the CPMP and CVMP have jointly revised this Note for Guidance taking into account the scientific development, and previous scientific explanatory notes and position papers in relation to minimising TSE risk. The revised Note for Guidance will be published on the website of DG Enterprise (http://pharmacos.eudra.org).
[3] CVMP Position paper on the assessment of the risk of transmission of animal spongiform encephalopathy agents by master seed materials used in the production of veterinary vaccines (EMEA/CVMP/019/01).
[4] For the context of this position paper, established WSs and WCBs shall mean WSs and WCBs used in the manufacture of already authorised products, which have been established before 1 July 2000, and which have been subjected to a properly conducted risk assessment by a Competent authority.
[5] For example WSs and WCBs of a vaccine antigen (subjected to a risk assessment by a competent authority as a constituent of an authorised mono-component or multi-component vaccine), incorporated in a new marketing authorisation application for a mono-component or multi-component vaccine.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 45
E-mail: mail@emea.eu.int http://www.eudra.eu.int
©EMEA 2002 Reproduction and/or distribution of this document is authorised for non commercial purposes only provided the EMEA is acknowledged

CPMP/CVMP guidance for re-establishment of existing working seeds and working cell banks

For WSs or WCBs which contain materials- where not all the relevant information is available to demonstrate compliance with the TSE Note for Guidance- even if there are no demonstrable TSE risks associated with their use, manufacturers are encouraged to replace them with new working seeds or working cell banks, prepared with materials for which all relevant information is available. This recommendation is considered as another step in the continuously evolving process of assuring the quality of medicinal products.

The following factors should be taken into account when considering the timeframe for re-establishing the WSs and WCBs:

- the nature of the materials used in establishing the working seeds or cell banks as identified in the risk assessment;
- the time necessary to establish and characterise the new working seeds and cell banks according to the current regulatory Note for Guidance without causing problems in supply;
- the stocks of intermediates/bulks or finished products prepared from the existing working seeds or cell banks, taking into account the mode of manufacture.

As soon as the WSs and WCBs have been re-established, they should be used for subsequent manufacture.

©EMEA 2002