Information for Members of the Working Group and relevant Stakeholders on Commission Directive 2003/32/EC for Medical Devices Utilising Tissues or Derivatives Originating from Animals for which a TSE Risk is Suspected.

Cell culture media

The specific reference in the Guidance Note to "cell culture media" does cover both Working Cell Banks and Master Cell Banks. The principles and practices on this specific subject by the medicinal sector should be adapted for the purposes of the medical device sector. (Refs. Joint CPMP/CVMP Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products, EMEA/CPMP/BWP/498/01 10 September 2002 and Position paper on re-establishment of working seeds and working cell banks using TSE compliant materials. EMEA/22314/02 10 September 2002).

Combination with medicinal substance

The combination of a medical device with an ancillary medicinal substance (i.e. utilising material of a TSE species) is within the scope of the Medical Devices Directive and the TSE Directive. The Notified Body should perform their review according to the existing procedures, including liaison with the relevant medicinal authorities in relation to the consultation for the medicinal component. For the latter the medicinal competent authority will apply their sector requirements for the assessment of the medicinal substance. The Notified Bodies should then proceed with the same review process as devices. For devices incorporating medicinal substances utilising non EDQM TSE certified materials notified bodies and national authorities should take account that the drug regulatory body would have covered the safety and quality of the medicinal substance, including TSE issues. This regulatory approach provides confidence in the safety of the final product as there are aspects of the TSE Directive (e.g. evaluation of alternative materials, justification rationale) which are not covered by the existing procedures alone.

Clinical Investigations

The review process for the safety and quality for clinical investigations of medical devices (i.e. those utilising material of TSE susceptible species) is the sole responsibility of the Competent Authority in which the application is made, by the manufacturer or his authorised representative.

"Discoveries" after September 2004

This matter relates to where a manufacturer of an existing medical device has verified their product to be outside the scope of Directive 2003/32/EC but is then informed by a third party the product, or its components, utilises material of TSE susceptible species. The manufacturer should explain the full details of the "discovery" and seek advice from their Notified Body. Before the start of any assessment process the Notified Body and its Competent Authority shall define the full regulatory process for these special circumstances. The Competent Authority should keep the other Member States informed of their activities.

New Medical Devices after April 2004

Where a manufacturer plans to introduce a new medical device utilising material of TSE susceptible species then it shall be assessed and evaluated in accordance with both Directives (i.e. Council Directive 93/42/EEC and Commission Directive 2003/32/EC, etc) before it is placed on the market.

Notified Body review of opinions from Member States.

For uniformity and consistency the principle activities by which the Notified Body should review the opinions received from their Coordinating Competent Authority were to :

- Collate all correspondence from their Coordinating CA;
- Identify all the opinions raised (which might be in different formats);
- Document their response or corrective actions to each point;
- Add additional information from manufacturers data file where necessary;
- Decide if they disagree or deviate" with any of the opinions from any Member State;
- Consult with their device Competent Authority if this was the case;
- Record their final decision on the complementary certification of the product;
- Notify the manufacturer and their device Competent Authority of this decision.

Where a Member State commented there was no mention of a relevant standard in the SER the Notified Body could record it was fully referenced in the manufacturers submission, it should not be viewed as a disagreement. If the comment stated there was no review of the clinical data to support the performance of the product, but there was extensive specific clinical data in the manufacturers file, this should not be viewed as a disagreement.

Original equipment manufacturer

During the conformity assessment procedure for a device, the manufacturer and/or the notified body shall take account of the results of any assessment and verification operations which, where appropriate, have been carried out in accordance with this Directive at an intermediate stage of manufacture. In application of this article to Directive 2003/32/EC, and in the case of OBL, where the original product has already been subject to an assessment according to this Directive, the consultation procedure with other Member States may be significantly reduced in terms of time.(OBL – Own Brand Labeller)

Renewal of Certificates

At the renewal of the Certificate the Notified Body shall perform a reassessment to verify its conformity with the requirements of the relevant Directives (i.e. Council Directive 93/432/EEC and Commission Directive 2003/32/EC).

Revision of MEDDEV 2.11.

The content and procedures of this guidance document should be revised by no later than June 2007. After adoption by the Medical Devices Experts Group it will be made publicly available to all stakeholders at the website of the European Commission.

Significant changes

Any changes in relation to the process of sourcing, collection and handling or inactivation / elimination that may modify the result of the manufacturers risk assessment dossier must be transmitted to the Notified Body for the purposes of an additional approval prior to its implementation (e.g. the use of a different abattoir for the primary raw material, a reclassification of the GBR level by the EFSA). These ongoing activities are to be performed by the Manufacturer and the Notified Body. Any new information on TSE risk, collected by the manufacturer and relevant for their devices, must be sent to their Notified Body. Any product involving a significant change that is assessed by the Notified Body, after consultation with their Competent Authority, as increasing the overall TSE risk will be regarded as a new product needing a renewed consultation procedure that references the previous consultation.