



## **EUCOMED Position Paper**

### **Regulation of animal-derived medical devices in the EU**

#### **Executive summary**

EUCOMED represents the interests of a majority of the companies involved in the development, manufacturing and distribution of medical devices in Europe, including those utilizing animal-derived tissues and their derivatives.

EUCOMED fully understands the concerns that have been generated by the recent increase in reported cases of Bovine Spongiform Encephalopathy (BSE) in Europe, whether this is a consequence of improved veterinary monitoring and cattle testing, or a real increase in the disease within the European cattle population. With uncertainty over the risks associated with the reported BSE increase, EUCOMED recognises the legitimacy of questions raised about the risks associated with ruminant-derived medical devices. This Position Paper explains the EUCOMED position concerning the current perception of such risks and recommends appropriate action in the best interests of both patients and clinicians.

#### **Current regulation and risk minimization**

The potential for unique risks from animal-derived medical devices has been recognised and has been subject to regulation for many years, specifically in the Medical Device Directive (93/42/EEC), where such devices were placed in the highest device risk class, i.e. Class III, regardless of clinical use and indication.

Class III medical devices can only have the CE Marking affixed after the issuing of a Design Certificate by an appropriate Notified Body accredited for evaluation of the device type concerned. Such design certification has always required that the particular Essential Requirements to prevent infection and microbial contamination from animal-derived devices are assessed and that the risk analysis and subsequent risk management processes have identified and minimized risks arising from the use of animal tissues and their derivatives.

The need for more detailed guidance to manufacturers and Notified Bodies in assessing and managing these Essential Requirements was recognised in

Europe, and two major initiatives were initiated by the Commission of the European Communities and supported by EUCOMED members:

- Draft MEDDEV 2.5/5 on assessment of medical devices incorporating materials of animal origin with respect to viruses and transmissible agents
- The mandated EN 12442 series of standards on the risk management, sourcing and handling, validation of process inactivation for medical devices of animal origin. These European standards are intended to be harmonized by the publication of the references in the Official Journal of the European Communities.

In many respects, these documents were based on previous Notes for Guidance issued by the European Committee for Proprietary Medicinal Products (CPMP) in relation to minimizing risks and validating process inactivation for pharmaceutical products; cross-references are included in both the draft MEDDEV 2.5/5 and the EN 12442 series.

During the period of development and approval of the EN 12442 series, these standards quickly became accepted by most manufacturers of animal-derived medical devices and Notified Bodies as an appropriate means for meeting the Essential Requirements. On a similar basis, the key elements for minimizing risk from Transmissible Spongiform Encephalopathies (TSEs) described within the German BfArM drug regulations have become a useful tool for risk assessment

Through utilising low BSE-risk cattle sources with strong veterinary controls, avoiding where possible the use of the higher risk tissues identified in both CPMP Guidance and "Specified Risk Material" Decision 2000/418/EC and 2001/2/EC, manufacturers of animal-derived medical devices have satisfied both European Notified Bodies and non-European Union regulatory authorities in relation to the safety and suitability for intended purpose and conformance to relevant essential requirements of these products.

Additionally, a number of manufacturers have ceased marketing some ruminant- derived medical devices where there were synthetic alternatives providing equal or better clinical utility.

### **Future regulation and risk minimization**

EUCOMED recognises that, whereas the previous history of risk minimization has proven adequate (no cases of TSE human transmission to humans from animal-derived medical devices have been identified to date), there are major concerns over possible risks due to the apparent spread of BSE and the possibility of inconsistency in risk management by both manufacturers and Notified Bodies. These concerns relate to lack of regulation over compliance with the actions necessary to assure low risk.

Early in 2000, EUCOMED was pleased to offer support to the Commission of the European Communities in reinforcing existing medical device regulation in relation to TSEs, following the removal of medical devices from the scope of the "Specified Risk Material" regulation in EU Decision 2000/418/EC.

EUCOMED accepts that, with the concerns raised by TSEs and the implementation of CPMP Guidance into pharmaceutical law, there is strong case to enshrine the approaches enshrined in EN 12442 and the draft MEDDEV 2.5/5 into medical device law, particularly in the light of previous experience of most manufacturers in following the critical elements in those documents.

The Commission of the European Communities has currently drafted a Commission Decision for such additional ruminant derived medical device regulation.

EUCOMED welcomes and will provide all necessary support to the earliest implementation of a Commission Decision based on this Working Paper. EUCOMED believes that the delay in issuing this decision has been a major factor in recent uncoordinated action by Member States in implementing their own regulations in relation to ruminant derived medical devices (especially since this draft Commission Decision was presented to all Member States in November 2000 with a subsequent general agreement on its provisions).

Whilst EUCOMED recognises the responsibility for Member States to safeguard the health of their citizens, where there is a theoretical risk such as contracting TSE infection from medical devices such unilateral action can only further undermine patient and clinician concerns and confidence in the CE Marking of medical devices. Only by co-ordinated action at the European level can there be consistent action that is based on current state of knowledge on BSE risks supported by the opinions of European Scientific Committees, that is likely to be accepted by non-EU regulatory authorities and which is essential for global trade and regulatory harmonization.

It is the EUCOMED position that early discussions be held with the Commission of the European Communities, Member States and Notified Bodies to prevent further short-term action by Member States in the current climate. EUCOMED intends to actively promote and support such discussions and invites Notified Bodies to support early initiatives to eliminate any concerns over the effectiveness of the Medical Device Directives in elimination of risks due to TSEs.

### **Clinical importance of animal derived medical devices**

EUCOMED is anxious to prevent a repeat of the mistakes of the SRM Decision 97/534/EC, which could have removed a large proportion of pharmaceuticals and devices from health care, thereby creating far more hazards than it was designed to prevent. Similar unilateral restrictions on use

of medical devices, purely on the basis of their animal or even ruminant origin, would repeat this error.

Animal tissues and their derivatives provide unique properties (including biocompatibility) and characteristics for which there often is no synthetic cost effective alternative. Such devices have a wide application such as heart valves, burn treatments, haemostats, tissue repair and wound dressings, and orthopaedic and vascular implants. The elimination of such devices from the market, purely on basis of a theoretical rather than actual TSE risk, would have detrimental impact of patient health and quality of life, clinical treatment options and cost of health care.

Whilst much remains uncertain over BSE, there are globally-accepted means of minimizing the risk. Bodies such as World Health Organisation, Office International des Epizooties carry out research and monitoring of the disease and advise on the geographical and tissue risks. These risk assessments have global credibility and are the basis of the critical elements of managing the risk within animal derived medical devices. Whilst recent BSE reporting in Europe and inclusion of bovine intestine in the list of specified risk materials may have altered some of the tissue and geographical risk evaluations, these are relatively minor changes and do not change the risk minimization approach described in the Commission of the European Communities draft Commission Decision or the CPMP approach as used for pharmaceuticals. The impact of these changes on most ruminant-derived medical devices will be to leave the previous assessments of low risk unchanged.

EUCOMED remains vigilant in the light of the BSE experience, which is likely to remain a legitimate area of concern for patients, clinicians, regulators and manufacturers for a number of years. The use of the globally-recognised approaches to risk minimization, as detailed in current draft MEDDEV 2.5/5 and EN 12442, should be enshrined in European regulation.

EUCOMED requests that Commission of the European Communities, Member States and Notified Bodies co-operate in the implementation of such regulation without delay and offers its full support towards finalizing the text of the necessary Decision.

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