

## **Bovine Spongiform Encephalopathy (BSE) - Use Reagent Grade Materials of Bovine Origin Med Practice**

**Document Number** PD2005\_200

**Publication date** 27-Jan-2005

**Functional Sub group** Clinical/ Patient Services - Pharmaceutical

**Summary** Directs hospitals to not use bovine derived materials in areas of medical practice unless the material has been evaluated by the TFA and has been included on the ARTG.

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**Applies to** Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations, NSW Ambulance Service, NSW Dept of Health, Public Hospitals

**Distributed to** Public Health System, NSW Ambulance Service, NSW Department of Health, Public Hospitals

**Review date** 27-Jan-2010

**File No.** 01/3892

**Previous reference** 2001/48

**Issue date** 15-Jun-2001

**Status** Active

**Director-General**

**Compliance with this policy directive is mandatory.**

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**CIRCULAR**

<b>File No</b>	01/3892
<b>Circular No</b>	2001/48
<b>Issued</b>	15 June 2001
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**BOVINE SPONGIOFORM ENCEPHALOPATHY (BSE)**

**USE OF REAGENT GRADE MATERIALS OF BOVINE ORIGIN IN MEDICAL PRACTICE**

Both the National Health and Medical Research Council's Special Expert Committee on Transmissible Spongiform Encephalopathies and the National Coordinating Committee on Therapeutic Goods have recently raised concerns about the potential for the transmission of BSE and its human counterpart variant Creutzfeld-Jacob Disease (vCJD). These concerns arise from the use of reagent grade products of bovine origin in certain areas of medical practice.

While there has as yet been no evidence of transmission of BSE through the use of medicines, the international regulatory community, including the Commonwealth's Therapeutic Goods Administration (TGA), is taking rigorous precautionary approach to ensuring that any potential risks are minimised. To this end, the TGA is reviewing medicines and medical devices, taking into account the nature and source of animal ingredients, as well as the manufacturing process involved, with a view to ensuring that risks of potential BSE transmission are minimised.

In the course of its evaluation of products, the TGA has become aware of practices in some hospitals in Australia that involve the use of unregistered products that contain bovine-derived ingredients. As these products have not been evaluated by the TGA, their potential risk of transmission of BSE is unknown and their use is therefore of concern.

Two specific examples of which the TGA is aware include hyaluronidase (where a reagent grade, bovine derived, product has been used in reproductive technology techniques) and bovine thrombin (where unregistered material has been used in procedures requiring haemostasis).

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Distributed in accordance with circular list(s):

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In accordance with the provisions incorporated in the Accounts and Audit Determination, the Board of Directors, Chief Executive Officers and their equivalents, within a public health organisation, shall be held responsible for ensuring the observance of Departmental policy (including circulars and procedure manuals) as issued by the Minister and the Director-General of the Department of Health.

In both cases, pharmaceutical grade materials are available which have been evaluated by the TGA and included on the Australian Register of Therapeutic Goods (ARTG).

Hospitals are therefore requested to ensure that bovine derived materials are not used in areas of medical practice unless the material has been evaluated by the TGA and has been included on the ARTG. All products included on the ARTG have the ARTG registration number (Aust R number) listed on the product label.

Michael Reid  
**Director-General**