



**Australian Government**  

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**Department of Health and Ageing**  
**Therapeutic Goods Administration**

Ms Patricia Reed  
Australian Bioenergetics Association Inc  
PO Box 296  
CREMORNE NSW 2090

Dear Patricia

Thank you for your letter requesting confirmation of our recent discussions relating to the use of EAV devices by practitioners post October this year.

Through the Therapeutic Goods Act 1989, the TGA regulates the **supply** of therapeutic goods to the market by the Australian sponsor of those goods. In simple terms, the Australian sponsor is considered to be either the manufacturer (if the goods are manufactured in Australia) or the importer (for overseas manufactured goods). It does not regulate the **use** of those goods.

EAV devices are currently excluded from the jurisdiction of the Act, by the Therapeutic Goods (Excluded Goods) Order No 1 of 1998. They will remain excluded until early October this year when, the first of the transition periods for the new medical devices regulatory framework expires. Beyond October, provided they fit the definition of a medical device given in section 41BD of the Act, they will require entry on to the Australian Register of Therapeutic Goods (ARTG) before the device can be **supplied**.

The devices currently in the hands of your practitioner membership will have already been supplied prior to October 2004, and practitioners using them will not be subject to the regulatory framework or penalties of the Act.

It should be noted however that importers or Australian manufacturers of such products, beyond October 2004, for supply to the market will be required to enter the products on to the Australian Register of Therapeutic Goods if they wish to continue supplying the devices.

Note also that supply, in the context of the Act has a wide ranging definition, and includes .... *by way of administration to, or application in the treatment of a person* ..... ' Thus, if a practitioner imports a **device direct or manufactures the device for use in their practice, they are considered a sponsor by the TGA**, and the imported or manufactured equipment is required to be entered on to the ARTG prior to use.

I trust this answers your query, but would be happy to discuss any further questions you have in this matter.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Michael Flood', written over a white background.

Michael Flood  
Office of Devices, Blood & Tissues <sup>v</sup>

2— July 2004