The Office of Devices Authorisation
PO Box 100,
WODEN ACT 2606
Email: devices@tga.gov.au

14 December 2010

Dear Sir/Madam

RE: RESPONSE TO TGA PROPOSED REGULATORY REFORMS

We understand the TGA is seeking comment from the dental industry in respect of proposed changes to the current TGA regulatory scheme. Critical Dental Pty Limited:

- Imports dental consumable products from various Asian countries;
- Wholesales and retails dental consumable products purchased in Australia form other importers; and
- Retails dental equipment manufactured in the USA, purchased in Australia.

2 proposed changes are of some concern to Critical Dental.

PROPOSAL 3(i)-ARTG Device Inclusion Methods

The current proposal requires sponsors to itemise the devices and/or various models that are supplied under a certain ARTG entry. As new models become available, sponsors will need to vary the TGA records to add any new models that become available.

This change substantially alters the existing regulatory arrangement for businesses and will result in a very large one-off cost to business, as well as significant ongoing costs.

New models for different devices are developed quite often, without having any impact on the device's use, operation, efficacy and patient health. The requirement for a variation to the TGA records for a new model should only apply when a device is significantly altered and its operation is different.

A preferable method would be to list the product names of devices in the ARTG entry, rather than a model name. This would allow model updates that do not considerably alter the operation of the device or impact upon patient health to occur without having the additional cost and waste of time caused by seeking a variation of the ARTG record.

Such alteration is costly and time consuming for businesses, such that such costs are becoming prohibitive.

Further a 2 year time frame for the implementation of any significant changes is much fairer to an industry that imports a large amount of goods and which therefore requires considerable time to make changes.

PROPOSAL 3(Iii) – Enhancing the Identification of Devices

The current proposal requires sponsors to publish the ARTG number on the information that accompanies a medical device.

The language in the discussion paper is unclear in that it states that all that would be required would be the addition of the ARTG number to the sponsor's contact details on the packaging. On the other hand, it also states that the ARTG number must be on the device itself unless it is impracticable and inappropriate to do so.

This needs to be clarified for the industry to be able to comply.

If the ARTG number has to be on the device itself in many, or even some cases, this change substantially alters the existing regulatory arrangement for businesses and will result in a very large one-off cost to business, as well as significant ongoing costs.

Most dental devices sold in Australia are imported and the compliance costs of having special product runs with ARTG numbers on devices destined for Australia will significantly and detrimentally impact upon the cost of health care in Australia. This is quite different to simply having something printed on packaging, such as a sponsor's details.

Certainly, if proposal 4 if adopted and device information, including the ARTG number, is already available on the TGA website, then producing it on the individual products is unnecessary and wasteful. It is a cost the industry can do without, and a cost the consumer can eventually do without.

Yours faithfully

Rebecca Edwards
Director
CRITICAL DENTAL PTY LIMITED