GUNZ dental
THE PEOPLE BEHIND THE PRODUCTS YOU TRUST

Office of Devices Authorisation
Therapeutic Goods Administration
P O Box 100
Woden ACT 2602

16 December 2010

Re: Reforms in the Medical Devices Regulatory Framework

Discussion Paper 25 October 2010

Further to the recent release of the discussion paper, I understand that the consultation meetings with the relevant industry sectors is now completed.

As a result of these discussions sessions together with the review of the proposed changes I hereby review the implications that these changes will make if implemented by the TGA.

Background

Gunz Dental is the largest Australian-owned importer and distributor of dental products in Australia and New Zealand. With three business units - Clinical, Equipment and Specialty (Laboratory, Implant and Orthodontics)

Founded in 1936, Gunz Dental now represents some 120 international and local manufacturers. With over 35,000 product lines, covered by 354 individual ARTG inclusions.

As a company Gunz Dental, maintains the highest quality of service and training, together with our dedicated adherence to TGA regulatory requirements.

Reforms Discussion that we are concerned about

Proposal 2B (ii) – Increasing pre-market scrutiny for implantable medical devices

This proposal will have significant impact on our company as we import Maxillo-Facial implants. The impost of a yet to be disclosed audit cost will not only impact on the viability of these devices, it will restrict the range, availability and promotional viability of these devices. The increased cost to market will result in increased cost burden to the end user and in-turn will result in a substantial cost burden to patients.

Proposal 2C(i) – Confidence building for EU Notified Bodies designated under the MRA

This proposal has implications for Gunz Dental if the international companies we represent have not had CE certificate issued by an MRA authorised certification body we are quite unclear on the constructive reason for this proposal. We have concerns with respect to why a MRA needs to be established and that TGA's financial commitment may be an open ended one.

Proposal 3 - Amending the way in which a medical device is included in the ARTG and enhancing identification of approved devices

3(i) – Amending the way a kind of device is included on the ARTG

Gunz Dental, supports this position, other than the complete identification of every device line item which we believe substantially alters the existing regulatory arrangements for our business. The impossible task will be to identify every line item of device that currently sits under a particular ARTG entry.

As explained with over 35,000 product lines, the size of one's application details with the variations that exist will increase regulatory burden at our level, it will require substantial IT burden and cost to maintain. To be subjected to the requirement for variation, not knowing how much this will cost and if a further TGA audit is required, will increase time to market, it will actively discourage companies and major suppliers from introducing updated devices into the Australian market place.

The proposal in its current form will result in very large initial one off cost to Gunz Dental and significant ongoing costs.

The idea of best practise will be reduced, together with the end users choice to offer substantial improvements to treatment planning as updated devices will not be potentially viable to introduce into the Australian market place.

3(ii) – Enhancing the identification of approved device

In accordance with regulation 10.2, Gunz Dental has a significant track and trace system already in place with the supply of devices distributed into the dental market. This proposal substantially alters the existing regulatory arrangements for our business and will require a massive injection of IT equipment and cost and at the pick, pack area where high tech identification of product and label requirements will be needed. The increase cost burden and increase process time for dispatch of product; together will result in a requirement of substantiate cost recovery.

The proposal in its current form will result in very large initial one off cost to Gunz Dental and significant ongoing costs. There is a point where companies can absorb this form of cost.

To the industry sector we predict that this will result in increased cost to the purchaser and subsequently increased cost to the Australian public and potentially place dental treatment outside of the budget of many Australian families.

As our end users are dental professionals and not the general public, the tracking of devices can be made by ARTG entry on the invoices and despatch notes thus allowing for correct identification of devices supplied.

Proposal 4 - Publication of device product information on the TGA Website

This proposal is totally impractical for dental supply company such as Gunz Dental.

The medical model that the TGA relies on for CMI and PMI data does not exist within this industry sector.

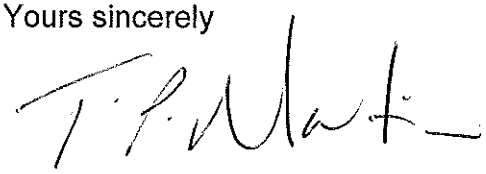
The Dental professional has access to significant MSDS data, explanatory notes, web access, and product information, on line and through their professional body the Australian Dentist Association. (ADA)

The increase in information required together with the duplication of information is substantial. There is no information within the TGA proposal to explain who is responsible for the information and its accuracy. The compliance costs that would be required represent an excessive burden for business which will escalate healthcare costs in Australia.

There is no public interest i having information on rejected applications in the domain, The TGA's primary responsibility is designed around the manufacture and supply of products on the Australian market and if an application is not approved an the product consequentially withheld from the supply, the TGA's responsibilities with respect to that device should end there.

Thank you for providing the opportunity to comment.

Yours sincerely



Trevor Martin

Managing Director

Gunz Dental