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ADIA Australian Dental Industry Association MEMBER

Office of Devices Authorisation

Therapeutic Goods Administration

P O Box 100

Woden ACT 2602

Re: Reforms in the Medical Devices Regulatory Framework

Discussion Paper 25 October 2010

I hereby review the implications that these changes will make if implemented by the TGA and how they will impact on our company and the Dental Industry.

Reforms Discussion that we are concerned about

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

This proposal will have significant impact on the Dental Industry. 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 internationally with the issuing of CE certificates from manufactures. If the international companies have not had CE certificate issued by an MRA authorised certification body we are quite unclear on the constructive reason for this proposal.

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

We do not support this position. The impossible task will be to identify every line item of device that currently sits under a particular ARTG entry. The discussion paper has made no reference to the changes in the definition of component parts and spare part allocations as related to the sale of capital equipment.

The size of one's application details with the variations that exist will increase regulatory burden at our level as well as the required IT burden and the 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.

3(ii) – Enhancing the identification of approved device

In accordance with regulation 10.2, we have introduced a significant tracking and trace system. This system allows us to distribute and track devices that we sell into the Australian dental market.

The increase cost burden and increase process time for dispatch of product; together will result in a requirement to increase prices to the end purchaser.

We also believe that this proposal will 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 us as an equipment supplier.

The medical model that the TGA relies on for CMI and PMI data does not exist within this industry sector. C Tick, product and circuit diagrams are readily available to installers and service people.

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

Borg Dental is supportive of any initiative that results in the improved safety and efficacy as outlined within the essential principals that underpin the inclusion of dental medical devices that are included on the Australian Register of Therapeutic Goods.

With the apparent lack of transparency by the TGA to identify the actual feedback drivers to substantiate the requirement to impose changes to Medical Devices Regulatory framework it is very difficult to support.

The overall ramification of increase cost to the industry, increase the cost burden to the Dental Professional and increased cost burden to the Australian public totally we see no reason to substantiate the introduction of proposal, 2b, 2Ci, 3i,3ii and 4 in their current form.

Yours faithfully

John Borg

Managing Director

Borg Dental