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Office of Devices Authorisation
Therapeutic Goods Administration
PO Box 100
Woden, ACT
2606

To whom it may concern:

As a dental product manufacturer, importer and distibutor here in Australia and as a member of the Austalian Dental Industry Association, I would like to respond to the reforms that the TGA is proposing to the framework surrounding a number of issues, some which do not directly impact us within the dental industry, however specifically those that relate to the ARTG Inclusion changes and enhancing identification of approved devices, would substantially alter the existing regulatory arrangements for business and will result in a very large initial one-off cost to business and significant ongoing costs. These need to be considered and reviewed further prior to implementation as they will could ultimately lead to increased costs in healthcare and subsequently impact on patient care.

While Erskine Dental is totally supportive of the TGA in ensuring the efficacy and integrity of medical devices of all classes, we believe that a process should be clear, concise and non subjective, and be applied with an element of understanding of 'real world' implications, never comprimising public safety but ensuring processes are not clouded in bureaucracy, and provide the public with practical process that deliver cost effective ethical representations of medical devices.

In reponse to the proposed changes:

Proposal 1 – **Reclassifcation of Joint Replacement** – this has no direct impact on our business therefore we are not in a position to comment.

Proposal 2 – **Third Party Assesment Bodies** – while it has little impact on our business, we suppport the change.

Proposal 2B (i) - **TGA Conformity Assessment Certificates** - this has no direct impact on our business therefore we are not in a position to comment.

Proposal 2B (ii) – **Pre-market Scrutiny for Implantable Medical Devices** – based on the current proposal we support it in principle.

Proposal 2C (i) – **EU Notified Bodies Confidence Building** – we understand the importance of this confidence building and strongly support this action but it needs to be monitored to ensure cost-effectiveness and financial commitment is not over extended.

Proposal 2C (ii) – **Australian Third Party Asessment Body Recognition** – Erskine Dental as a manufacturer welcomes this initiative.

Proposal 3 (i) – **ARTG Inclusion Changes** - There remains some ambiquity surrounding this proposal, which would need to be defined or an alternate solution sought. A cost benefit analysis needs to be undertaken looking at and measuring business compliance costs as part of a Regulatory Impact Statement. As indicated this would substanilayy alter our existing regulatory arrangements and result in a large one-off up front cost with substantial ongoing costs for our business in the future. We therefore cannot support this proposal in this current form.

Proposal 3 (ii) – **Enhancing identification of Approved Devices** – Until it is clearly outlined and determined exactly where this ARTG number 'must' be included, it is difficult to support in this current ambiquous form. A large proportion of product is received from overseas suppliers, and the stark reality is that while developed, Australia is a small percentage of the world market, and any attempt to forcabilty have this number included on product labelling and packaging will only cause increases in costs or unavailability to Australian patients and consumers. The increased direct costs and additional associated costs will greatly impact Australia businesses and the whole medical and dental industry. Simpler, more cost effective and realistic alternatives should be sought, or a complete impact study to determine the real costs involved and efects to the market should be undertaken prior to any further implementation of this proposal.

Proposal 4 – **Publishing device information on the Website** – Again while transparency is supported, the need or requirement for lower risk therapeutic devices would be far outweighed by the increased costs to connsumers and health professionals. In higher risk classifications we fully support this proposal as in these higher risk category efficacy and patient safety are of utmost importane, yet we believe it is unwarranted in the lower risk devices.

We thank you for this opportunity to respond to these proposals, and trust that our comments will be considered in part with other submissions you have received from the medical and dental industries. Please keep us informed of any further developments in regards to these proposals. If you require anything further, do not hesitate to contact me if necessary on (02) 6568 3773. Thank you.

Yours Truly,

Glenn Jasprizza
General Manager
Erskine Dental