triodent
SIMPLE SOLUTIONS FOR SMART DENTISTS

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Comment on Reforms in the Medical Devices Regulatory Framework

To follow, please find comments on the following proposed reforms:

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

Triodent is a manufacturer of Class1 dental devices, the majority of which are consumables. The proposed requirement to identify different models of device would be an extremely difficult exercise without a very clear understanding of what a model is and what changes constitute a new model. Changes are often made to our devices in response to our customer's needs. TGA must clearly define a 'model' and which changes are significant enough to constitute a new model.

The TGA's proposal, if adopted in its current form, substantially alters the existing regulatory arrangements for businesses and will result in a very large initial one-off cost to.business and significant ongoing costs.

Proposal 3(ii) – Enhancing the Identification of approved devices:

Triodent is a manufacturer of Class1 dental devices. The majority of these devices are small consumable devices which, even as bulk packs, are small packs. Space on these packs is minimal and the requirement to place an ARTG number on the pack would result in Australia only packaging. Australia is a relatively small market internationally and separate packaging would ultimately lead to added cost to health professionals and consumers.

The TGA's proposal, if adopted in its current form, substantially alters the existing regulatory arrangements for businesses and will result in a very large initial one-off cost to.business and significant ongoing costs.

Yours sincerely

Greer Fricker
Regulatory Affairs