



## TGA Fee Proposal Formally Rejected By Dental Industry

Proposals to levy a new fee on suppliers of medical devices have been formally rejected by the peak business organisation representing dental product manufacturers and suppliers, the Australian Dental Industry Association (ADIA).

The new fee has been proposed by the Therapeutic Goods Administration (TGA) for businesses applying to place new low-risk medical devices on the Australian Register of Therapeutic Goods (ARTG), the list of therapeutic products that can be lawfully supplied in Australia.

“Australia’s dental industry is primarily composed of small businesses with less than ten employees. Like all small businesses they are already under pressure and the TGA’s new fee just makes things harder,” said Troy Williams, ADIA Chief Executive Officer.

Whereas business previously could place low-risk medical devices on the ARTG without paying an application fee, the TGA has proposed that from 1 July 2018 there will be a cost of \$530 for each new entry. It is estimated that for these small businesses the cost will be between \$4,240 and \$13,250 per year.

The ADIA membership supplies around ninety-five percent of the medical devices used in dental practices nation-wide and the advice from these suppliers is the new fee will make it commercially unsustainable to introduce new specialised products that are likely to be sold in low-volumes.

“SMEs across the dental industry have made it clear this new \$530 fee creates a new barrier to the entry of new and innovative products into the Australian marketplace. The losers will be dental professionals and their patients that won’t be able to access these new advances,” Mr Williams said.

For small businesses in the dental industry the TGA’s new fee is likely to negate the benefits flowing from a comprehensive reform of medicines and medical device regulation resulting from amendments to the Therapeutic Goods Act 1989 (Cth) passed by the parliament in 2017 and 2018.

“When it comes to reducing the compliance burden on small businesses in the dental industry, and the medical technology sector more broadly, it’s looking like a case of one step forward and two steps back,” Mr Williams said.

In response to stakeholder consultations ADIA has formally written to the TGA and the Minister for Health rejecting the proposed new fee.

Ends.

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