



Australian Government



Australian  
**Small Business and  
Family Enterprise**  
Ombudsman

15 March 2021

Manager  
Fees and Charges  
Therapeutic Goods Administration  
136 Narrabundah Lane  
Symonston ACT 2609

*via email: TGA FeesAndCharges@health.gov.au*

Dear Sir/Madam

**Public Consultation – Fees and charges proposal 2021-22**

We provide the following recommendations to the TGA on your proposed fees and charges and regulation of small businesses:

- 1. Stakeholder engagement.** Before making regulatory changes, the TGA should engage closely with small businesses to avoid unintended consequences. For example, the current proposed changes to the definition of custom-made medical devices have been implemented very quickly and have unintended consequences. The Orthodontics industry, especially orthodontic laboratories, which are often sole trader businesses run out of the family home, will potentially be subject to huge unexpected fees due to the changes. We have heard from small businesses who are concerned about these changes and are currently investigating the matter further.
- 2. Flexibility.** The rigidity of the TGA rules can result in businesses paying fees while never actually using the product, with the TGA unable to administer refunds or alter the process. For example, we were contacted by a small business owner who missed the deadline to defer registration on the Australian Register of Therapeutic Goods (ARTG) for a device that never entered the country due to COVID-19. Despite the small business owner never using the device and declaring \$0 turnover, the TGA advised there was no capacity under the Act or Regulations to waive the fees. This meant the business had to bear the \$1820 expense for two years on the ARTG for no benefit. This rigidity leads to wasted resources of both the TGA and small businesses. The TGA should wherever possible incorporate a more flexible approach.
- 3. Simpler system.** The TGA should not punish small businesses for genuine mistakes, but instead seek to both simplify its systems and work with small businesses to help them avoid mistakes in future. This would help lead to faster and more efficient approvals, which is good for businesses and reduces costs for the TGA.

Thank you for the opportunity to comment. If you would like to discuss this matter further, please contact Mr Luke Collins on 02 6213 7540 or at [luke.collins@asbfeo.gov.au](mailto:luke.collins@asbfeo.gov.au).

Yours sincerely

**The Hon. Bruce Billson**  
Australian Small Business and Family Enterprise Ombudsman

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