



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

on [redacted] or at [redacted]

Yours sincerely

[redacted]
Australian Small Business and Family Enterprise Ombudsman

T 1300 650 460 E info@asbfeo.gov.au

www.asbfeo.gov.au

Office of the Australian Small Business and Family Enterprise Ombudsman
GPO Box 1791, Canberra City ACT 2601