

22 February 2022

Therapeutic Goods Administration
PO Box 100 Woden
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[REDACTED]

Reference: Fees and Charges proposal 2022-23 Consultation Paper– Version 1.0 /February 2022

Thank you for providing the opportunity to respond to the proposed fees and charges for 2022-23.

The vast majority of ATSA members are dealing with assistive technology (AT) that are Class 1 Medical devices, which in the main are relatively low in volume and are registered on the ARTG.

Preferred Option 3 where “applying the indexation factor, fees and charges would be rounded to the nearest \$10 for items less than \$10,000 and to the nearest \$100 for items \$10,000 and above “will effectively increase the cost to assistive technology suppliers at a rate that is significantly higher than the proposed 2.6% indexation.

While ATSA and its members understand costs to run a business are growing, in percentage terms the proposed increase in Options 2 and 3 is above any CPI growth when the \$10 rounding factor is considered. Despite the impact of the \$10 rounding approach from previous years that is compounding, annual increases have been continually applied. Only a monopoly situation can get away with such increases.

The TGA and Government may see the increases in dollar terms are relatively small, e.g. \$10 increase per year, per service for Class 1 devices, however the price review should address whether this is an accurate reflection of the increase of resource to manage the effort.

Most of the affected businesses are SMEs and not large multinationals. When you add the number of required listings for a typical business this increase is significant and local businesses can be placed at a competitive disadvantage. An offshore business who has volume can leverage against their high-volume production to offset the increases in fees, while local businesses cannot. Government needs to fund agencies like the TGA and stop shifting cost to industry to fund non direct service functions and to invest in better systems that reduce the cost to do business with the TGA such as the Digital Transformation Update.



The regular price increases from the TGA are in effect an indirect tax on the industry to fund regulation/compliance activity. ATSA's view is this is not a fee for service model or a true cost recovery model.

Just as Covid-19 has resulted in additional costs for the TGA, it has also had a significant impact on the cost of importing materials and AT devices into Australia for our members who have borne the additional freight and import costs that have arisen during these unprecedented times.

ATSA is unable to support any proposed increases to the fees and is therefore supporting Option 1: No Increase in Fees and Charges, Any of the other proposed Options

- May stifle innovation of new AT
- Allow ongoing increases to recoup higher running costs at the TGA that do not reflect actual costs of activity related to the ARTG which is unreasonable.
- Force companies to start to trim what categories they 'buy', which will result in incorrect classifications, or companies arguing that the product shouldn't be classified at all, resulting in poor controls for the supply of AT.
- Reflect an increase which in percentage terms since 2017 have not been justifiable. Disadvantage local businesses who do not have the international volumes to offset the increases.

To have good regulation, we need fair regulation from our government, at a fair price.

David Sinclair
Executive Officer

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