

8<sup>th</sup> March 2021

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**Reference: Fees and Charges proposal 2021-22 Consultation Paper– Version 1.0 /February 2021**

Thank you for providing the opportunity to respond to the proposed fees and charges for 2021-22.

It is with great disappointment that ATSA again has for the third time, found it necessary to raise concerns with continuing percentage fee increases.

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, but more than exceed any special dispensation therefore are required to be 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 1.05% indexation.

While ATSA and its members understand costs to run a business are forever 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 is this a true reflection of the increase of resource to manage the effort?

Most of the businesses effected are not large multinationals, they are in general SMEs and when you add up the number of required listing for a typical business this increase is not insignificant. This places competitive disadvantage for the local businesses. An offshore business who has volume can leverage

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against their high-volume production to offset the increases in fees, they cannot. **Simple actions and ill-conceived policies do have consequences.** Government needs to seriously consider how it funds 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.

The regular price increases from the TGA is to allow it to meet its obligations that includes additional demands by Government. Due to the cost recovery requirement that is placed on the TGA, the effect is an indirect tax on the industry to fund non regulation/compliance activity. ATSA's view is this is not a fee for service model or a true cost recovery model as professed.

The impact of these fees has already been acknowledged with the welcomed concession that was introduced for Class 1 ARTG listing for product that will be exported, with a fee reduction down from the \$530 to \$90 in October 2018. This does not go far enough.

ATSA and its membership support the ARTG regulation structure as it has successfully pushed "cowboys" out of from supplying AT. Historically the registration was cost effective and created "good" business practises for the sector. We are now greatly concerned that due to the high cost now in place, it will encourage unscrupulous businesses to fall back into inappropriate practises, resulting in the compromise of safe supply of AT.

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

- Put a burden on and stifle innovation of new AT, and therefore patient/user outcomes will likely suffer
- 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

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



David Sinclair  
Executive Officer



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