

25th February 2020

Regulatory Practice & Support Division | Health Products Regulation Group
Regulatory Services & Drug Control Branch
Australian Government Department of Health
PO Box 100
Wooden ACT 2606

Sent mail; TGA FeesAndCharges@health.gov.au

Reference: Fees and Charges proposal 2020-21 – Version 1.0 January 2020

Thank you for providing the opportunity to respond to the proposed fees and charges for 2020-21.

I understand that some of our members will respond directly. Below is the summary of the accumulative responses via ATSA.

It is with great disappointment that ATSA again has found it necessary to raise concerns with continuing fee increases, that in practise is greater than the stated average of 1.95%.

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.

The proposed increase will demonstrate that since 2017, for Class 1 items on the ARTG of between 550% to 560% (dependant on the application of rounding for 2020-21) for the registration of a new device and 25% for listing renewal. ATSA was led to believe that back in 2018 when the application from no fee to a fee of \$530 to register a Class1 was to be reviewed and to assess the impact on the sector. It appears that the only review was to continue to increase the fees without consideration of the cost implications of the sponsors of these goods or the users.

While ATSA and its members understand costs to run a business is forever growing, in percentage terms the proposed increases, in part due to the \$10 rounding factor, is well above any CPI growth. 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.

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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. One business has been working with the TGA to rationalise their listings but, they are still looking at a \$1500 increase in fees on last year. This is a small family business that sell items that are low in value, low in volume, that will be forced to increase their prices for aids that assist the aged and disability sector.

This places competitive disadvantage for the local business. An offshore business who has volume can leverage 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.

- It will put a burden on and stifle innovation of new AT, and therefore patient/user outcomes will likely suffer
- Ongoing increases to recoup higher running costs at the TGA that do not reflect actual costs of activity related to the ARTG are unreasonable.
- Companies will 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.

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- In percentage terms the increases since 2017 are not justifiable.
- Disadvantaging local business 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.

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