atsa
Assistive Technology
Suppliers Australasia

6th February 2019

George Masri
Regulatory Services and Drug Control Branch
Therapeutic Goods Administration
Department of Health
PO Box 100
Wooden ACT 2606

Reference: D18-11360694

Dear Mr Masri,

Thank you for your letter of 12th December 2018 requesting communication of the proposed fees and charges for 2019-20 along with the request for feedback on the Fees and Charges Consultation paper Dec 2018.

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

In summary the industry is very unhappy with the introduction in July 2018 of an application fee of $530 to register a Class 1 medical device on the Australian Register of Therapeutic Goods (ARTG). In addition, the annual fee for a Class 1 ARTG listing moved to $90 from $80 (12.5% increase), now additional increases are proposed.

It has been recognised and welcomed that a concession 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.

If the preferred option is adopted, then the costs for registration of a Class 1 would increase to $540, and the annual fee would move to $100 (in effect another 10% increase on the 2018 increase).

These combined increases for 24 months to the sector equates to 25% increase on annual fees and a 540% plus increase to register a Class 1 in real terms. This well surpasses the inferred 2.05% increase indicated.

Industry understands the cost involved to run a business or service along with the associated increasing pressures, however the proposed increases are exceptional and well above CPI in real terms. When you consider that we are yet to fully understand the real impact that the just introduced $530 registration fee will have. ATSA suggests that the planning for an increase is very premature.

As an example of one business, their costs for 2019, based on the current fees, anticipates an increase of $13,200 in TGA compliance costs for their Class1 ARTG requirements. These are for items that are low value and or low sales but still require registration to be maintained. They do not anticipate that they will be able to pass

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the costs onto customers as it would make products non-competitive. Therefore, they are considering discontinuing the supply and de-list which limits consumer choice.

Another business has indicated it was intending to expand its business range but due to the fees now in place, it is reconsidering.

When the original registration scheme was put in to place circa 2002, it acted as a deterrent to "cowboys" suppling AT, as the registration was cost effective and encouraged "good" business practices for the sector. Several businesses have expressed concern that due to the high costs now in place, it will encourage fewer businesses to fully comply and encourage errant behaviours, resulting in the compromise to safety of AT supplied.

ATSA believed the new $530 fee was to be monitored and reviewed with the intention to amend once the implication of the new regime was understood. This was confirmed in writing on the 16th July 2018, with the TGA, ref D18-10724019. At that time, I cautioned any delay in the review of this fee will most likely prove to be damaging to the supply of AT devices to those who need them, seniors and those with disability who are some of Australia's most vulnerable and disadvantaged citizens. However, it appears that the fee is to be increased regardless.

ATSA is unable to support any proposed changes to the fees. This is due to;

- Increases since July 2018 for registration of a product as a Class 1 onto the ARTG have not been reviewed to determine the impact of their introduction to the AT sector. It is noted that a change was required within 3 months of its introduction for Export products. This action highlights that the $530 cost to register had a negative impact on Australia's export market.
- The combined increase on the annual maintenance fee over 2 years, is estimated to be 25%, far above CPI, and the inferred 2.05% (preferred option)

[redacted]

David Sinclair
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