

NATERA, Julian

From: Nicole McLay <Nicole.McLay@tga.gov.au>
Sent: Tuesday, 10 March 2015 7:19 AM
Subject: FW: FY2015-16 TGA Fees & Charges [SEC=UNCLASSIFIED]

Nicole McLay FCPA
Assistant Secretary, Regulatory Business Services
Therapeutic Goods Administration
Department of Health
Ph 02 6221 6910

From: John Skerritt
Sent: Monday, 9 March 2015 8:48:45 PM
To: Nicole McLay; Samantha Palmer
Subject: FW: FY2015-16 TGA Fees & Charges [SEC=UNCLASSIFIED]

We can report the net impact on the dental companies to be in the range of \$ 1000- a few thousand per year when we do the Minsub. Not a show stopper.

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
National Manager, Therapeutic Goods Administration

Deputy Secretary, Department of Health
PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6232 8200 Fax: (02) 6203 1265
Email: John.Skerritt@tga.gov.au

From: Troy Williams - ADIA [mailto:troy.williams@adia.org.au]
Sent: Monday, 9 March 2015 8:45 PM
To: John Skerritt
Subject: RE: FY2015-16 TGA Fees & Charges [SEC=UNCLASSIFIED]

Dear John

Thanks for your email and I am happy to provide clarification.

The envisaged reduction of free and charges by five percent was factored into the review but that was insufficient to off-set the higher fees payable associated with changing the basis of the exemption from a "low turnover" to a "no supply". As many of the products are instruments of various kinds the "public health benefit" would be difficult to quantify and would probably result in a larger administrative workload – happy to be corrected.

The compliance costs to businesses in the dental industry have been estimated in the range of \$2,500 to \$4,000 which is why there is no net benefit, the higher fees that become payable under the new scheme are not off-set by reduced compliance costs.

I hope that this explanation clarifies the challenge that the dental industry faces with respect to the proposal.

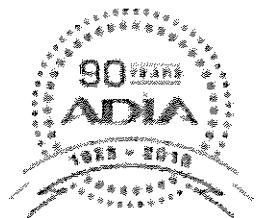
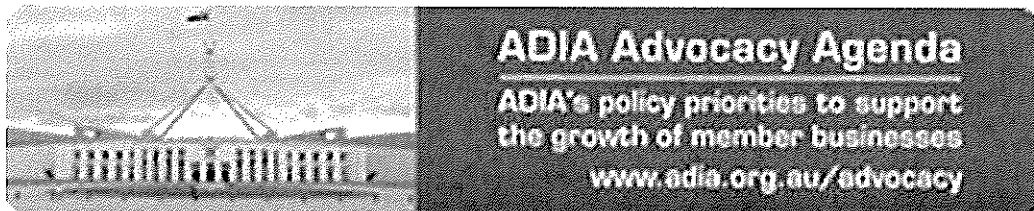
Regards

Troy

Troy R Williams FAIM MAICD
Chief Executive Officer ■ Australian Dental Industry Association



National Office: GPO Box 960, Sydney, NSW, 2001
Government Affairs: GPO Box 1, Canberra, ACT, 2601
t: 1300 943 094 ■ f: 1300 943 794 ■ m: 0488 660 188
Twitter: [@AusDental](https://twitter.com/AusDental) ■ e: troy.williams@adia.org.au ■ www.adia.org.au



On 27 February 2015, the Australian Government announced a proposal to withdraw a range of medical devices from the Australian Register of Medical Devices (ARMD) and to amend the Therapeutic Goods Act 1989 to allow for the withdrawal of the devices if the Minister is satisfied that the withdrawal is in the public interest.

From: John Skerritt [mailto:John.Skerritt@tga.gov.au]
Sent: Monday, 9 March 2015 7:52 PM
To: Troy Williams - ADIA
Subject: RE: FY2015-16 TGA Fees & Charges [SEC=UNCLASSIFIED]

Troy

I think that there may be a misunderstanding – we are proposing a 5 % reduction in annual charges for class 2a as well as class 2b, 3 and AIMD devices. In addition, where there would be public health impacts from the withdrawal of the devices it is possible for the sponsor to apply for a waiver of charges.

I was unable to provide the RIS figures to you at the time I wrote my letter to you, but expect that OBPR will clear the RIS in the next couple of days, and then we/ they will be in a position to make it public. It shows that the savings to industry from the proposed changes to the LVT scheme are substantial. The figures that will provided will have been checked in fine detail by the OBPR.

John

Adjunct Prof John Skerritt FTSE FIPAA (Vic)
National Manager, Therapeutic Goods Administration

Deputy Secretary, Department of Health
PO Box 100 Woden ACT 2606 Australia

Phone: (02) 6232 8200 Fax: (02) 6203 1265
Email: John.Skerritt@tga.gov.au

From: Troy Williams - ADIA [mailto:troy.williams@adia.org.au]
Sent: Monday, 9 March 2015 7:46 PM
To: John Skerritt
Subject: RE: FY2015-16 TGA Fees & Charges [SEC=UNCLASSIFIED]

Dear John

Thanks for your email and recap on the approach. The formula and the regulatory amendment process is understood and the background information was, as always helpful. The challenge in balancing the competing budget interests is understood along with modelling the reform options – the Australian Dental Industry Association (ADIA) makes extensive use of economists and consultants in similar disciplines to product much of our industry data and it is always a large investment. In that context, ADIA will no oppose either of the two fee increases.

With respect the proposed amendments to the Low Value Turnover (LVT) scheme, based upon an assessment by member businesses and the brief assessment that the Therapeutic Goods Administration (TGA) undertook on our behalf, it's difficult to envisage a scenario based upon the current reform proposal that ADIA could support. Having spoken to businesses which supply higher-risk medical devices, the attractiveness of the proposal from their perspective is understood as it alleviates the higher fees paid; however, for the dental industry, and any cohort of business that sells low to medium risk medical devices (i.e. Class 2a), it is unlikely that the proposal would ever work in their favour. The reduced costs in terms of compliance are more than off-set by higher fees and charges which was demonstrated by the TGA's assessment as it was as a result of further work by member businesses – indeed, it is unlikely that a single business in the dental industry will benefit. There are also some concerns that the impact statement may be premised on a false set of assumptions with respect to the costs incurred by industry and that these may be over-estimated.

Do you believe there is a way to deliver a reform proposal that, as a minimum, does not disadvantage the dental industry? The tight timeframe to work through the issue is understood.

Thanks for your comments on my trip which is focussed on a meeting of the association of International Dental Manufacturers (IDM) that accompanies the *IDS Cologne* dental exhibition which attracts around 120,000 stakeholders from across the dental community.

John, I'll call upon my return next week to discuss the LVT issue but any preliminary guidance is appreciated.

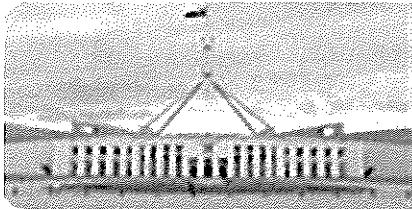
Thanks and regards

Troy

Troy R Williams FAIM MAICD
Chief Executive Officer ■ Australian Dental Industry Association

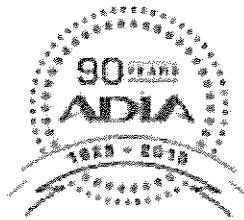


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ADIA Advocacy Agenda

ADIA's policy priorities to support the growth of member businesses
www.adia.org.au/advocacy



ADIA and ACCI are pleased to bring you this update on the progress of our advocacy efforts and our continued advocacy in the lead up to the 2015-16 Budget. As you will recall, the government has already announced a 2.5% increase in the base budget for the 2015-16 Budget, which is equivalent to a 1.43% increase in the cost of living. This is a significant increase in the cost of living, and it is important that the government takes steps to ensure that the cost of living is not further increased.

From: John Skerritt [mailto:John.Skerritt@tga.gov.au]
Sent: Monday, 9 March 2015 6:40 PM
To: Troy Williams - ADIA
Cc: John Skerritt
Subject: RE: FY2015-16 TGA Fees & Charges [SEC=UNCLASSIFIED]

Troy

I trust that you had a good trip overseas.

On fees and charges, the decisions on changes are made by the Executive Council (Ministers and Governor General, as it involves regulatory change), on the advice of A/Minister Nash.

In most previous years, TGA has requested an average figure based on the mean of the Consumer and Wage Price Indices for the 12 month period up to 30 September of the preceding year. For the current period, that figure is 2.5 %.

However this year we propose to suggest to Minister Nash that she considers one of two lower figures – the final decision will be hers:

- Either 1.43 % which is the known direct increases in service costs for 2015/16. For example, rent and make-good is a significant part of this, as we have an odd lease where we not only have a 3 % increase in payments next year but have to do re-painting and re-carpeting of the building regularly.
- Or the 1.43 % plus about 0.6 % of known salary increments. These are the salary increases that about 1/3 of the junior staff and middle managers receive if they are able to obtain increments (e.g. an exec assistant going from clerk/ APS grade 4.1. to 4.2) – these are compulsory. We made an initial underestimate of the cost as under the TGA special account model we not only have to cover the increase in fortnightly pay for these folks but at this point in time also have to provision for their recreation leave and long service leave.

Even if she approves the higher of the two figures, it will still be a challenging year financially for TGA. We will have to absorb the costs of implementation of the accepted recommendations at the Medicines and devices review, and even if they are deregulatory in nature we have to do extensive RIS costings and this will likely require contracting one of the big 4 consulting companies to do arms-length figures – plus the cost of policy staff to design regulatory changes.

The other thing that keeps me awake budget wise is that if the government agrees to an increase of say 2 % for public servant salaries that's almost another \$ \$ 2 m we need to absorb on a per annum basis.

But the bigger message we communicated at the bilaterals last week was that with the Meds Review it is likely that the scope of what TGA regulates will change and we will have to rebase all our fees and charges in 15/16 through an activity based costing exercise for future years.

Finally, do we need to discuss the ADIA letter regarding the LVT scheme ? I had hoped to discuss it with you last Tuesday.

Regards

John Skerritt

**Adjunct Prof John Skerritt FTSE FIPAA (Vic)
National Manager, Therapeutic Goods Administration**

Deputy Secretary, Department of Health
PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6232 8200 Fax: (02) 6203 1265
Email: John.Skerritt@tga.gov.au

From: Troy Williams - ADIA [<mailto:troy.williams@adia.org.au>]
Sent: Monday, 9 March 2015 4:35 PM
To: John Skerritt
Subject: FY2015-16 TGA Fees & Charges

Dear John

Firstly, I hope that you are well and please accept my apologies for missing the bilateral meeting last week.

Can you please confirm the increase in fees and charges of 1.43%? I understand that it may be around 0.50% higher given an issue in calculating wage costs. Either way it is something that we are likely to support but I wanted to be sure of getting the correct advice to members.

Thanks and regards

Troy

Troy R Williams
Chief Executive Officer
Australian Dental Industry Assoc.

GPO Box 960, Sydney, NSW, 2001
t: +61 [0]2 9319 5631
m: 0488 660 188 e:troy.williams@adia.org.au

www.adia.org.au

- Sent from an iPhone5 running on Telstra 4g

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