

**NATERA, Julian**

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**From:** Rachel Corey <Rachel.Corey@tga.gov.au> on behalf of TGA Parliamentary <TGA.Parliamentary@tga.gov.au>  
**Sent:** Wednesday, 24 June 2015 9:58 AM  
**Subject:** For response - MC15-011910 - Due 30/6/15 [DLM=For-Official-Use-Only]  
**Attachments:** MC15-011910 - Williams (ADIA) - Low Value Turnover Scheme - 12 June 2015 - Further to MC15-007924.pdf  
  
**Importance:** High

Good morning Nicole,

We have received a subsequent piece of corre from Troy Williams and we would be grateful for your assistance with preparing a response.

Correspondence number MC15-011910.

Marked for urgent ministerial response.

Due to Parliamentary – Tuesday 30 June 2015, Dep Sec cleared.

Notes: PDF also at R15/502055

Kind regards,  
Rachel

**TGA Parliamentary**  
Lisa Selems / Tara Condon / Rachel Corey  
Business Capability & Committee Support Section  
Regulatory Engagement, Education & Planning Branch

Phone: 02 6232 8069 / 02 6232 8826 / 02 6232 8224  
Mobile: 0412 052 461  
Email: [tga.parliamentary@tga.gov.au](mailto:tga.parliamentary@tga.gov.au)

**Therapeutic Goods Administration**  
Department of Health  
PO Box 100  
Woden ACT 2606 Australia  
[www.tga.gov.au](http://www.tga.gov.au)

due MPEC 3/7/15 2:00pm  
due MO 3/7/15 4:30pm

RECEIVED

Ref: 11.11.14K — 12 June 2015

24 JUN 2015

Division: TGA  
Minister: FN  
Milestone: 12 June 2015

INFO   
VIP   
PM

Link to MCIS-007924

Sen. Hon. Fiona Nash  
Assistant Minister for Health  
PO Box 6100 – The Senate  
Parliament House  
CANBERRA ACT 2600

Dear Minister

**RE: TGA Low Value Turnover Scheme**

Thank you for your correspondence (date unclear) in response to representations made by the Australian Dental Industry Association (ADIA) that set out concerns with charges levied by the Therapeutic Goods Administration (TGA), specifically the abolition of the Low Value Turnover (LVT) exemption scheme and its replacement with the Annual Charges Exemption (ACE) scheme. As the peak business organisation representing manufacturers and suppliers of dental products, ADIA takes this opportunity to draw your attention to an unfortunate error in the advice that you have received.

Your correspondence states that the TGA modelling used to prepare the Regulation Impact Statement (RIS) showed that the costs will be lower for the majority of small businesses; however, such an assertion is undermined as the TGA modelling was deficient and did not include its own analysis of the higher fees that small businesses in the dental products and surgical instruments sector will pay.

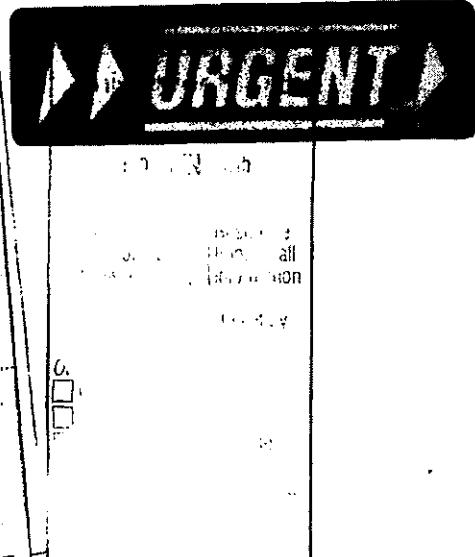
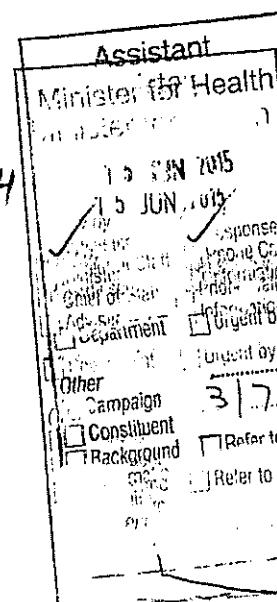
As referenced in previous correspondence, the TGA undertook an analysis of five businesses (selected at random) in the dental industry to assess the impact of the changes which identified that ARTG changes will increase by around thirty percent. There is no reason to believe that a different or larger sample of businesses would have yielded a different result.

The RIS associated with these reforms was inexpertly prepared and omits any reference to the TGA's own assessment that charges will rise for many small businesses in the dental industry and surgical products sector. In essence, arguments that the introduction of the ACE scheme will reduce compliance costs cannot be substantiated.

The major concern is one of a failure of process where the TGA has failed to tender proper advice to you and the Office of Best Practice Regulation (OBPR) concerning the impact of these changes on small businesses in the dental industry and other surgical instruments. The RIS contains no detailed analysis on the impacts of businesses in this sector and entirely omits reference to the fact that the TGA's own analysis identified a likely increase in TGA charges of around thirty percent.

Australian Dental  
Industry Association

ADIA



Representing Dental Industry Excellence



Australian Dental Industry Association Limited  
ABN 32 003 314 396

National Office: GPO Box 960, Sydney, NSW, 2001  
Government Affairs: GPO Box 1, Canberra, ACT, 2601  
e: national.office@adia.org.au www.adia.org.au  
t: 1300 943 094 f: 1300 943 794

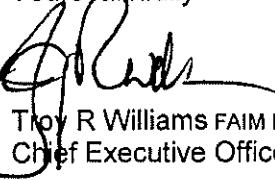
The TGA has stated that the underpinning rationale for this change is to reduce the regulatory compliance burden on the industry; however, there is no strong case upon which this can be made. Although the ACE does reduce the red-tape as a result of simplified exemption (estimated to be \$1,000 per business per annum), using the TGA's own analysis all five businesses sampled would still have higher compliance costs as a result of the reforms.

The TGA has suggested that a business could exercise the option of seeking an exemption on the basis of the public health and financial viability test under the new ACE scheme; however, the TGA has failed to recognise that the compliance burden in business associated with the public health and financial viability test is actually higher than the former LVT scheme.

The pending introduction of the ACE scheme is already harming small businesses, impeding their ability to grow, create jobs and operate sustainably. ADIA has been advised that these small businesses are planning to withdraw products from the ARTG which will reduce competition in the sector. Indeed, in evidence to estimates hearings of the Senate Community Affairs Legislation committee the TGA National Manager, Adj. Prof. John Skerritt, readily offered his thoughts that small businesses would withdraw product if there was another supplier – an outcome that reduces competition.

Minister, as the abolition of the LVT scheme to replace it with the ACE scheme was based upon the conclusions of an inexpertly prepared RIS, ADIA once again requests a more comprehensive review of the reforms.

Yours faithfully



Troy R Williams FAIM MAICD  
Chief Executive Officer