

NATERA, Julian

From: Tara Condon <Tara.Condon@tga.gov.au> on behalf of TGA Parliamentary <TGA.Parliamentary@tga.gov.au>
Sent: Thursday, 18 June 2015 12:20 PM
Subject: For information - MC15-011445 - ADIA [DLM=For-Official-Use-Only]
Attachments: MC15-011445 - Williams - TGA Low Value Turnover Scheme - 12 June 2015 - For information only.tr5

Good afternoon Nicole

For your information, please find attached further correspondence from ADIA regarding the ACE scheme.

Kind regards
Tara

TGA Parliamentary
Lisa Selems / Tara Condon
Business Capability & Committee Support Section
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Ref. 11.11.14K

17 JUN 2015

Division: TGA	<input type="checkbox"/> INFO	<input type="checkbox"/> VIP
Minister: FN	<input type="checkbox"/> P	<input type="checkbox"/> PM
Milestone: 17 June 2015	<input type="checkbox"/> 10L <input type="checkbox"/> 15L <input type="checkbox"/> 20L	

Link to MC15-001P24

Hon. Sussan Ley MP
Minister for Health
PO Box 6022 – House of Representatives
Parliament House
CANBERRA ACT 2600

Australian Dental
Industry Association

ADIA

Minister for Health
Minister for Sport

16 JUN 2015

Reply by Minister Chief of Staff Adviser

Action Response Phone Call Information

Asst Min for Min Department Urgent by _____

Other Campaign Constituent Background Information Required Refer to *Nash*

Comments: _____

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18 JUN 2015
Assistant
Office of the
Hon Sussan Ley MP

17 JUN 2015

Reply by Minister Chief of Staff Adviser

Action Response Phone Call Information

Department Urgent by _____

Other Campaign Constituent Background Information Required Refer to _____

Dear Minister

RE: TGA Low Value Turnover Scheme

As the peak business organisation representing manufacturers and suppliers of dental products, the Australian Dental Industry Association (ADIA) has made representations to the Assistant Minister for Health concerning 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 you have received a copy of the Minister's latest advice to ADIA on this matter (copy enclosed), ADIA takes this opportunity to draw your attention to an unfortunate error in the advice that the Minister has received.

The enclosed 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 the 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.



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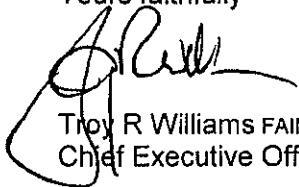
The TGA has stated that the underpinning rationale for this change is to reduce the regulatory compliance burden on the industry; however, there is no strong case upon which this can be made. Although the ACE does reduce the red-tape as a result of simplified exemption (estimated to be \$1,000 per business 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

Encl.



Senator the Hon Fiona Nash

Assistant Minister for Health

Senator for New South Wales

Deputy Leader of the Nationals in the Senate

RECD: 12 June 2015
REF 1 11-11-14K
REF 2 11-1-1-14

COPY

Ref No: MC15- 007924

Mr Troy Williams
Chief Executive Officer
Australian Dental Industry Association
GPO Box 960
SYDNEY NSW 2001

Troy
Dear Mr Williams

Thank you for your letter of 8 May 2015 regarding the review of the Therapeutic Goods Administration's (TGA) low value turnover (LVT) annual charge exemption scheme and your continued engagement with the TGA on this matter.

The LVT scheme was introduced in 1990 and predates the introduction of the Australian Government cost recovery policy (CR policy). The review of the LVT scheme found that; the scheme was not only inconsistent with the CR policy, as contrary to the intentions of the scheme the top 20 claimants are receiving over 50 per cent of total exemptions meaning that annual charges must be set higher overall (including for small business) in order to fund those exemptions, but was also costly and complex for sponsors. The TGA continues to receive feedback that some sponsors, especially small business, do not seek LVT exemptions because they consider that the cost of preparing and submitting an LVT application outweighs the benefit. The proposed annual charges exemption (ACE) scheme is designed in such a way that it not only complies with the CR policy but would also simplify participation requirements and reduce regulatory red tape for business.

The Regulation Impact Statement (RIS) identifies an annual saving to industry of \$3 million in administrative costs and \$2.4 million in LVT application fees. It is acknowledged that the replacement of the LVT scheme with the new ACE scheme will have varying impacts on individual sponsors, but overall would achieve a benefit to industry. The TGA is not aiming to generate more annual charge revenue from this change, and will have a reduction in revenue of \$2.4 million from the current application fees.

I note that in your discussions with the TGA, you nominated five sponsors who may pay more in annual charges in the first year of implementation of the scheme if they keep their current number of products on the ARTG. However these costings do not appear to take into account the saving they would achieve as they would not be required to prepare and submit an application for seeking the exemption which equates to, on average, around \$1,000/sponsor per annum. Further, they do not

appear to take into account that some speciality devices may have their annual charges waived if they meet the public health and financial viability tests under the new provision being introduced as part of the ACE scheme. To reduce this impact further the sponsors may choose to cancel some of their low turnover products which may not be financially viable if an annual charge is paid. Of course this action would be a commercial decision of the sponsor.

Under the proposed scheme, all products would qualify for an exemption if they were granted LVT exemptions on the basis of \$0 turnover in the last two financial years rather than since their entry on the ARTG. In addition, all new medical devices (including class 1 medical devices) would automatically qualify for the exemption until they commence turnover. This is a significant advantage of the new scheme for class 1 medical device sponsors because they generally do not seek exemption under the current scheme as the LVT application fee of \$155 alone is far more than the annual charge of \$80. In addition, medical device classes IIa and above would benefit from the 5 per cent reduction in annual charges from 1 July 2015 and the proposed waiver provisions.

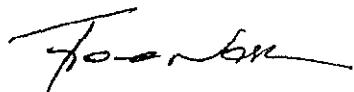
In view of the above I believe the proposed scheme simplifies the participation requirements, in particular for the small businesses that were not participating in the LVT scheme, and will significantly reduce red tape and regulatory burden for industry. The TGA modelling shows that costs will be lower for the majority of small businesses.

I am advised that the TGA, as part of its governance arrangements to implement the new ACE scheme, will monitor the impact on all stakeholders. Consideration will be given to all industry sectors in this process.

Should you have any further questions regarding this matter, you may contact the TGA via email to ace.exemption@tga.gov.au or by contacting Ms Nicole McLay on 02 6221 6910.

Thank you for raising this matter.

Yours sincerely



Fiona Nash

11/11/2015

cc The Hon Sussan Ley MP, Minister for Health and Minister for Sport