

26/05 2015 TUE 15:09 FAX

RECEIVED 26 MAY 2015

27 MAY 2015

Division TGA
Milestone FW

INFO
VIP
PM

MCIS-010083

001/001

Assistant Minister for Health

27 MAY 2015

Reply by
 Minister
 Chief of Staff
 Adviser

Action
 Response
 Priority Call
 Information

Department
 Urgent

Other
 Campaign
 Constituent
 Background Information Required
 Refer to

Comments:

link to MCIS-067924
Ref: 11.11.14K — 26 May 2015
link to MCIS-010091
link to MCIS-010067
Hon. Karen L. Andrews MP
Parl. Sec. to the Minister for Industry & Science
PO Box 6022 - House of Representatives
Parliament House
CANBERRA ACT 2600
MCIS-010086

Australian Dental Industry Association



Parl. Sec. to the Minister for Industry and Science

VIP Parl. Sec. Reply (5 days)
 Parl. Sec. Reply (5 days)
 Departmental Reply

Priority / COS:

27 MAY 2015 DIV: Corporate

Replied in the PSO
 For appropriate action
 For information (NFA)
 Preferable to raising Parl. Sec
 Referral Health

Dear Ms Andrews

RE: TGA Regulatory Reform – Low value turnover scheme abolition

As the peak business organisation representing manufacturers and suppliers of dental products, the Australian Dental Industry Association (ADIA) seeks your assistance in securing an urgent review of proposed reforms to the charges levied by the Therapeutic Goods Administration (TGA). Under the guise of red-tape reduction, the net impact is to increase by around thirty percent the charges paid by the dental industry to the TGA.

The TGA is the nation's regulator for medicines and medical devices which operates on a cost-recovery basis. A considerable portion of the TGA's revenue is derived by businesses that pay to place entries on the Australian Register of Therapeutic Goods (ARTG), a listing of medical devices that can be lawfully supplied in Australia.

Currently, the regulation allows a business to claim an exemption from certain TGA charges if the sale of products produces revenue that is fifteen times (or less) the TGA charge. The proposed reform eliminates the exemption the moment the product is sold. There are some associated reductions in business red-tape as a result of revised TGA's documentary requirements; however, any savings to businesses in the dental industry are entirely negated by higher TGA charges.

There is a degree of urgency as the changes are expected to be approved by the Federal Executive Council on Thursday, 28 May 2015, and commence on Wednesday, 1 July 2015.

Of significant concern is that the Regulatory Impact Statement (RIS) prepared by the TGA in support of the proposal omitted any reference to the higher fees that the dental industry will face. It was on the basis of the flawed RIS that the Assistant Minister for Health is understood to have accepted the need for reform.

The outcome of the regulatory reform spells bad news for jobs in the industry as the viability of businesses that sell dental products will come into question. Patient treatment options will also be limited as the higher TGA fees are likely to result in some products being withdrawn from the market.

Any assistance that you are able to provide in terms of drawing attention to this matter with a view to securing a proper analysis of the proposed reform is appreciated.

Yours faithfully


Troy R. Williams FAIM MAICD
Chief Executive Officer

RECEIVED

28 MAY 2015

Division Minister

Milestone: 10 15 20

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CAMPAIGN ASSOCIATE

Any assistance that you are able to provide is appreciated!



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Representing Dental Industry Excellence



Parl Corro
 <ParlCorro@industry.gov.au>
 26/05/2015 16:40

To "referrals@health.gov.au" <referrals@health.gov.au>,
 cc
 bcc
 Subject Possible referral from Industry (MC15-002353)
 [SEC=UNCLASSIFIED]

1 attachment



MC15-002353.pdf

UNCLASSIFIED

Good afternoon

The attached correspondence has been received by the Hon Karen Andrews MP, Parliamentary Secretary to the Minister for Industry and Science. However the issue(s) raised appear to fall within your department's portfolio.

It would be appreciated if you could review the correspondence and advise us by **29 May 2015** if the issue(s) fall within your department's portfolio responsibilities. Please note that we will not forward the hard copy to you unless requested to do so.

Regards

Steve Currie
 Parliamentary Services | Communications
 Corporate Network
 (02) 6102 8194 | steve.currie@industry.gov.au
 Department of Industry and Science | www.industry.gov.au

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