



Sharon Claydon MP

FEDERAL MEMBER FOR NEWCASTLE

28 May 2015

Senator the Hon. Fiona Nash
Assistant Minister for Health
PO Box 6100
Parliament House
CANBERRA ACT 2600

Dear Assistant Minister

Please find enclosed correspondence from Mr Troy R. Williams, Chief Executive Officer of the Australian Dental Industry Association.

Mr Williams has raised concerns with me regarding the proposed reforms to the charges levied by the Therapeutic Goods Administration (TGA).

I ask that you please consider the issues Mr Williams has raised and provide me with a copy of your response in due course.

Yours sincerely

Sharon Claydon MP
Federal Member for Newcastle

Encl.

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| Assistant Minister for Health | |
| 12 JUN 2015 | |
| Reply by | Action |
| <input checked="" type="checkbox"/> Minister | <input checked="" type="checkbox"/> Response |
| <input type="checkbox"/> Chief of Staff | <input type="checkbox"/> Phone Call |
| <input type="checkbox"/> Adviser | <input type="checkbox"/> Information |
| <input type="checkbox"/> Department | <input type="checkbox"/> Urgent by |
| Other | |
| <input type="checkbox"/> Campaign | |
| <input type="checkbox"/> Constituent | |
| <input type="checkbox"/> Background Information Required | <input type="checkbox"/> Refer to |
| Comments | |

link to:
MCIS-007924

Simple case letter
attached response
MCIS-011043

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| RECEIVED | |
| 12 JUN 2015 | |
| Division: TGA | INFO |
| Minister: FN | |
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Ref: 11.11.14K — 26 May 2015

Ms. Sharon C. Claydon MP
Member for Newcastle
427 Hunter Street
NEWCASTLE NSW 2300

28 MAY 2015

Dear Ms Claydon

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

Any assistance that you are able to provide is appreciated!



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