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 29/05/2015 15:16

R1032

To "referrals@health.gov.au" <referrals@health.gov.au>
 cc
 bcc
 Subject Possible referral from Industry (MC15-002404)
 [SEC=UNCLASSIFIED]

1 attachment



MC15-002404.pdf

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RECEIVED	
- 7 JUN 2015	
Division: 76A	INFO <input checked="" type="checkbox"/> VIP <input type="checkbox"/> PM <input type="checkbox"/>
Minister: FW	
Milestone: 10 <input type="checkbox"/> 15 <input type="checkbox"/> 20 <input checked="" type="checkbox"/>	

Good afternoon

link to MC15-007924

The attached correspondence has been received by the Hon Ian Macfarlane MP, 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 **3 June 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
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Department of Industry and Science | www.industry.gov.au

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

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M(15) - 002404

Australian Dental Industry Association

ADIA

28/5/15

Ref: 11.11.14K — 26 May 2015

Hon. Ian E. Macfarlane MP
Minister for Industry & Science
PO Box 6022 - House of Representatives
Parliament House
CANBERRA ACT 2600

MINISTER FOR INDUSTRY AND SCIENCE

VIP Minister reply - 5 days

Minister reply - 5 days

Departmental reply

Adviser/COS

DL: DB r 29 MAY 2015

Replied in the MO

For appropriate action

For Information (NFA)

Prepare brief advising Minister

Referral to Health

Dear Minister

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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Representing Dental Industry Excellence

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