RIS / 504005

NATERA, Julian

From: Frank Marando <Frank.Marando@tga.gov.au> on behalf of GSU PC <GSUPC@tga.gov.au>
Sent: Tuesday, 9 June 2015 12:46 PM
Subject: RE: ACTION: Urgent - Input to PM&C meeting brief - Australian Dental Industry Association - Due back to PM&C 2pm Wednesday 10/6 [DLM=For-Official-Use-Only]
Attachments: MB15-000518 - Meeting with ADIA Council - June 2015 (draft).DOCX

Hi all,

We have just been through the process of preparing a Briefing Note for the Minister's attendance at the ADIA Council meeting.

It is currently with Lisa Studdert for clearance, and also requires John Skerritt's clearance by COB tomorrow.

Unless there are any objections, once cleared by Lisa and John, I suggest providing PM&C with a copy of this Briefing Note as our input.

I have attached the current draft for your information.

Thanks
Frank

From: Tara Condon **On Behalf Of** TGA Parliamentary
Sent: Tuesday, 9 June 2015 12:33 PM
To: Nicole McLay; Terry Lee; GSU PC
Cc: Vinod Mahajan; Will Freebairn
Subject: ACTION: Urgent - Input to PM&C meeting brief - Australian Dental Industry Association - Due back to PM&C 2pm Wednesday 10/6 [DLM=For-Official-Use-Only]
Importance: High

Good afternoon Nicole, Terry, ROU

PM&C has been asked to prepare a meeting brief for the Parliamentary Secretary to the Prime Minister in advance of his meeting with the Australian Dental Industry Association and is seeking our urgent input by 2pm tomorrow – *please refer below to key points of discussion.*

In meeting this timeframe, we would be grateful for your *input as soon as possible* – TGA Parliamentary will obtain final Dep Sec clearance of our consolidated input.

Additionally, a copy of our recent response to Mr Williams (MC15-007924) as signed by the Assistant Minister is attached for information.

If you have any questions, please do not hesitate to call.

Thank you
Tara

TGA Parliamentary
Lisa Selems / Tara Condon
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From: [redacted] [mailto:[redacted]
Sent: Tuesday, 9 June 2015 11:58 AM
To: TGA Parliamentary; [redacted]
Subject: PSPM meeting brief - ADIA [SEC=UNCLASSIFIED]

UNCLASSIFIED

Good Morning

We have been asked to prepare a meeting brief for the Parliamentary Secretary to the Prime Minister in advance of his meeting with the Australian Dental Industry Association.

We understand the matters raised at the meeting could include those raised in ADIA's recent correspondence with the Prime Minister, the Parliamentary Secretary and the Minister for Health regarding:

- fees and charges levied by the Therapeutic Goods Administration (specifically to abolish a fee exemption widely used by small businesses);
- the timing of approval by the Federal Executive Council to these changes;
- the Regulatory Impact Statement prepared by the TGA in support of the proposal; and
- any other sensitivities you consider may be raised.

I have attached recent correspondence for your information.

I would greatly appreciate any input you can provide on these matters, as well as advice on any other sensitivities you consider may be raised (e.g. the progress of the National Partnership Agreement on public dental services). We have been asked to provide a brief by COB, Thursday, so any input you can provide by 2:00pm, Wednesday would be greatly appreciated

Please let me know if you wish to discuss further.

Kind Regards,
[redacted]

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Meeting Briefing
For Information

MB15-000518
Version: (0)

To: **Minister Ley**

Meeting: **Australian Dental Industry Association (ADIA) Council Meeting**

Location: **Private Dining Room 3, Parliament House**

Purpose: **To brief you on issues that may be raised by attendees at the ADIA Council meeting**

Clearance:

Contact Officer:	*Dr Lisa Studdert*	*First Assistant Secretary, Market Authorisation Division*	Ph: (02) 6232 8087
Clearance Officer:	*Prof John Skerritt*	*National Manager, Therapeutic Goods Administration*	_____ *Clearance Officer Signature* …../…../2015

Australian Dental Industry Association
The ADIA represents the interest of manufacturers and suppliers of dental products on commercial, technical and regulatory issues. They report to have a membership that supply more than 97% of the dental products in Australia.

ADIA business activities include meeting with government on regulatory issues, developing growth and innovation opportunities for the sector, and supporting their members through continuing professional development programs and hosting networking events and industry exhibitions.

Funding history
The Department has not provided funding to ADIA over the last 5 years.

Chief Executive Officer (CEO), ADIA
Mr Troy Williams took up the position of CEO, ADIA, in 2010. He has represented the manufacturing industry and small business on several government and non-government committees including the Therapeutic Goods Administration's (TGA) Regulatory and Technical Consultative Forum (RegTech) for medical devices.

Key Topics:

1. Review of Medicines and Medical Devices Regulation
The *Review of Medicines and Medical Devices Regulation* received submissions from the Australian Dental Association and the ADIA. In addition, the Expert Panel met with Mr Williams, CEO, ADIA, after the consultation period for stage one of the Review closed.

The ADIA was particularly interested to ensure low risk devices remain under the auspices of the *Therapeutic Goods Act 1989.*

2. Regulation of Custom-Made Dental Devices
The ADIA does not believe that custom-made dental devices are adequately regulated. The ADIA claims that custom-made dental devices which are sourced from overseas appear to escape TGA scrutiny. The ADIA supports the approach used in the UK where patients receiving a dental appliance are offered a statement of manufacture which is also held by practitioners for the lifetime of the device.

The regulation of custom-made devices has been discussed at quarterly RegTech meetings held between TGA and peak industry bodies, including the ADIA.

3. Infringement Notices
The ADIA has raised the possibility of the TGA issuing infringement notices to those who procure dental products from overseas outside of the regulatory framework.

The level of evidence required to support an infringement notice is the same as that required for a court action. In addition, if an infringement notice is issued, no further action in relation to that infringement may be taken by the TGA and there is no record of either a conviction for an offence, nor a judgment of the Federal Court against the non-compliant person, resulting in a less-deterrent effect.

4. Annual Charge Exemption Scheme
The ADIA believes the proposal to replace the current low value turnover (LVT) scheme with the annual charge exemption scheme will disadvantage small businesses in the sector.

The proposed scheme simplifies the participation requirements, in particular for the small businesses who were not participating in the LVT scheme, and will significantly reduce red tape and regulatory burden for industry. However, the TGA will monitor the impact of the new scheme on the therapeutic goods industry.

5. Child Dental Benefits Schedule
The Child Dental Benefits Schedule (CDBS) started on 1 January 2014 and replaced the Medicare Teen Dental Plan. Around three million children aged 2-17 years in families who meet a means test will be eligible each year.

6. National Partnership Agreement on Adult Public Dental Services
In the 2015-16 Budget, the Australian Government announced funding for a 12 month National Partnership Agreement (NPA) on Adult Public Dental Services. This new NPA will provide the states and territories $155 million during 2015-16 for additional services to around 178,000 adult dental patients. Negotiations with the states and territories will commence shortly.

The states and territories will also have access to the CDBS for a further 12 months, from 1 July 2015 to 30 June 2016. The Minister will be making changes to the Rules to formalise the extension of access as soon as possible.

Background

1. Review of Medicines and Medical Devices Regulation

The independent expert panel's first Report on the *Review of Medicines and Medical Devices Regulation* was provided to Government on 31 March 2015.

The second and final Report, addressing the regulation of complementary medicines and the advertising framework for therapeutic goods, is expected mid-2015. Following this, the full Recommendations of the Review will be a matter for Government consideration. There will be opportunities for consultation with consumers, industry, business and affected regulators in relation to the Recommendations of the Expert Panel.

The Review is consistent with the Government's policy of reduced regulatory burden on business and individuals and is relevant to the Government's agendas on Smaller Government, and Innovation and Competitiveness.

The Government is committed to ensuring the safety, efficacy and effectiveness of medical devices in Australia, and that approvals and post-market assessment is underpinned by a sustainable, transparent, and streamlined regulatory framework.

The Review received submissions from the Australian Dental Association and the ADIA. In addition, the Expert Panel met with Mr Troy Williams, Chief Executive Officer, ADIA, after the consultation period for stage one of the Review closed.

The ADIA was particularly interested to ensure low risk devices remain under the auspices of the *Therapeutic Goods Act 1989.*

2. Regulation of Custom-Made Dental Devices

The ADIA does not believe that custom-made dental devices are adequately regulated. The ADIA claims that custom-made dental devices which are sourced from overseas appear to escape TGA scrutiny. The ADIA supports the approach used in the UK and Europe where patients receiving a dental appliance are offered a statement of manufacture which is also held by practitioners for the lifetime of the device.

Dental prostheses are regulated under the *Therapeutic Goods Act 1989* (the Act), with some dental prostheses, such as crowns and bridgework, regarded as custom-made medical devices. Custom-made devices are required to meet appropriate requirements but are exempt from inclusion in the Australian Register of Therapeutic Goods (ARTG). Manufacturers and suppliers must hold appropriate information to be able to demonstrate that their devices are safe and perform as intended, and report to the TGA about any malfunctions or problems with the design, production, etc. of the device. These requirements apply irrespective of the country of origin of a custom-made device.

Under the Therapeutic Goods (Medical Devices) Regulations 2002, the manufacturer or sponsor of a custom-made device must provide the TGA with information about the device. To date this has been done via email with information stored electronically and not scrutinised. ADIA has requested that TGA develop a database to make notification easier and TGA is currently considering the design and scope of this project.

The TGA has been actively working with dental industry peak associations regarding regulation of custom-made devices and raising awareness of regulatory requirements. Adjunct Professor Skerritt has discussed the issue with the Australian Dental Association and the Dental Board of Australia. These organisations have undertaken to remind dentists of their legal obligations in relation to imported dental products.

While the TGA is unable to mandate the source of devices or materials used by Australian dentists, dentists and others who import and/or supply custom-made devices are, by definition, the 'sponsors' of these medical devices and therefore take on full responsibility for ensuring the products meet the appropriate Australian regulatory requirements. Any concerns about the quality, safety or performance of specific products should be reported to the TGA via its Incident Reporting and Investigation Scheme. Such reports enable the TGA to investigate and test the materials used in the construction of the devices.

Additionally, the regulation of custom-made devices has been discussed at quarterly RegTech meetings held between TGA and peak industry bodies, including the ADIA.

3. Infringement Notices

The ADIA has raised the possibility of the TGA issuing infringement notices to those who procure dental products from overseas outside of the regulatory framework.

The Act was amended in 2006 to introduce infringement notices as part of the enforcement package introduced in the Act. The relevant provisions under the Act are sections 42YJ and 42YK. Sections 42YJ and 42YK authorise the making of regulations that enables a person who is alleged to have committed an offence against the Act or to have contravened a civil penalty provision to pay to the Commonwealth a specified penalty as an alternative to prosecution or civil penalty proceedings against that person.

An infringement notice gives a person, to whom the notice is issued, the option of either paying the penalty set out in the notice to expiate the offence or contravention of a civil penalty provision or electing to have the matter dealt with by a court.

The option to issue infringement notices only arises following a decision by the TGA to take legal action against a person for non-compliance with a regulatory requirement involving a strict liability offence or for civil penalties.

Where the notice relates to a strict liability offence under the Act, the maximum amount payable by an individual cannot exceed 20% of the maximum amount that could have been imposed on the individual for that offence (which for unlawful importation of a medical device would be 20% of $340,000). The maximum amount payable by a company cannot exceed 5 times the amount payable by an individual (which in this case would be 5 x $68,000). However, the strict liability offences that would be most relevant here are predicated on the use of the medical device being likely to cause harm or injury to a person.

If an infringement notice is issued and payment is made in respect of that notice, no further action in relation to that infringement may be taken by the TGA and there is no record of either a conviction for an offence, nor a judgment of the Federal Court against the non-compliant person.

If a person issued with an infringement notice disputes their liability, they may instead elect to have the matter dealt with by a court in which case the matter is dealt with as a criminal offence or civil contravention, whichever is relevant.

Details of the infringement notices such as the content of the notices, payment of the pecuniary penalty, contesting of notices, and withdrawal of notices, are set out in detail in the regulations.

Due to the level of evidence required to support an infringement notice is the same as that required for a court action, the TGA has followed the latter course because the potential outcome (a conviction) has a stronger deterrent effect.

4. Annual Charge Exemption Scheme

The ADIA believes the proposal to replace the current low value turnover (LVT) scheme with the annual charge exemption scheme will disadvantage small businesses in the sector.

The TGA recovers the cost of its regulatory activities through fees and charges from the industry it regulates. Costs of pharmacovigilance and other post market monitoring and compliance activities are recovered through annual charges levied on therapeutic goods on the ARTG. Different levels of pharmacovigilance are required for different classes of therapeutic goods depending on the level of risk the good could pose. Annual charges have been set to reflect the level of pharmacovigilance and post market work required for the regulated good rather than the size of the individual business. For example, the annual charge for a class 1 medical device (other than a class1 medical device that has a measuring function or is supplied in a sterile state) is $80 whereas for a high risk prescription medicine (biologic) the annual charge is $6,585.

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% 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.

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 don't 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 a 5% reduction in annual charges from 1 July 2015 and a new provision in the regulations that allows for waiver of the annual charge if certain criteria are met in relation to public health and financial viability.

In view of the above, the proposed scheme simplifies the participation requirements, in particular for small businesses, and will significantly reduce red tape and regulatory burden for industry. The TGA will monitor the impact of the new scheme on the therapeutic goods industry.

5. Child Dental Benefits Schedule

The Child Dental Benefits Schedule (CDBS) started on 1 January 2014 and replaced the Medicare Teen Dental Plan. Around three million children aged 2-17 years in families who meet a means test will be eligible each year.

The CDBS provides a benefit entitlement of $1,000 per eligible child (capped over a two year period) for basic dental services.

The CDBS has provided $359 million in benefits and delivered 5.6 million services to over 1 million Australian children (1,047,192) since it commenced on 1 January 2014 (to end March 2015).

CDBS services can be provided by dentists or dental specialists in either public or private dental sectors. Dental hygienists, dental therapists, oral health therapists and dental prosthetists can also provide services under the CDBS on behalf of a dentist or dental specialist.

6. National Partnership Agreement on Adult Public Dental Services

In the 2015-16 Budget, the Australian Government announced funding for a 12 month National Partnership Agreement (NPA) on Adult Public Dental Services. This new NPA will provide the states and territories $155 million during 2015-16 for additional services to around 178,000 adult dental patients. Negotiations with the states and territories will commence shortly.

The states and territories will also have access to the CDBS for a further 12 months, from 1 July 2015 to 30 June 2016. The Minister will be making changes to the Rules to formalise the extension of access as soon as possible.

The new NPA in combination with continued access to the CDBS will see the states and territories being able to access over $200 million in funding in 2015-16.

The Australian Government will use 2015-16 to consider future options for dental reform in the context of the White Paper on the Reform of the Federation.