MCD REGULATORY OPERATIONS UNIT COVER SHEET

EACorro reference 433169 **TRIM reference** R15/440789

PRIORITY	ACTION	TIMELINE
Low ☐	Response ☐	Executive 5/6/15
Routine ☑	Clearance ☑	Date due back 10/6/15
Urgent ☐	Signature ☐	Time due __/__/__
Overdue ☐	Advice sought ☐	Due to Minister __/__/__
	Information only ☐	Due to Secretary __/__/__
	Action required ☐	Due to Dep Sec __/__/__

To ~~John Skerritt~~ ⇒ Larry Kelly A/g National Manager _____ Signature

Through Lisa Studdert N/A ☐ _____ 9/6 Signature

_____ N/A ☐ _____ Signature

_____ N/A ☐ _____ Signature

_____ N/A ☐ _____ Signature

Subject MB15-000518 - Meeting with ADIA Council

Return to Frank Marando / Jenny Mason x8672 / x8167 Extension

Comments

The attached Briefing Note has been requested for Minister Ley's attendance at the ADIA Council Meeting.

Cleared input has been received from BPRDD and ACD. Within TGA input has been cleared through DAB and RBS.

For your comment / clearance. See edits thanks

Thank you.

Fe.

Executive clearance

Signed ☐
Approved ☐
Resubmit ☐ Date for resub __/__/__
Not approved ☐

_____ Signature

Date __/__/__

Australian Government
Department of Health

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:	*Dr Larry Kelly*	*Acting National Manager, Therapeutic Goods Administration*	*Clearance Officer Signature* 10/6/2015

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 and has made representations to the Prime Minister's Office to have the scheme delayed and amended. Regulations are in place for a 1 July 2015 start.

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 as a whole. 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. These changes are set out in the Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulation 2015, which was approved by the Governor-General on 28 May 2015 and commences on 1 July 2015.

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.

Frank Marando

From: GSU PC
Subject: FW: FOR ACTION: New MEETING Brief Request - Due:4pm 10/06/2015 - MB15-000518 - Meeting with Australian Dental Industry Advisory Council - 16 June 2015 [SEC=UNCLASSIFIED]

MEETING BRIEF - MB15-000518 - Meeting with Australian Dental Industry Advisory Council - 16 June 2015

Please note that the briefing request form is an email which can be found at the bottom of this email

Main Carriage:	TGA **It is assumed your area has accepted carriage of this request unless you advise us otherwise. This includes liaising with any area from which input is required.**
Other Areas with possible input:	As determined by TGA **The cc'ing of other areas is only an early identification by MAPS Branch of likely areas that may need to be consulted.**
Due Date	4pm 10/06/2015
Clearance	**FAS/State Manager level but may be delegated to AS subject to FAS approval.** **Check with your local BMU.**

Cleared Briefing Notes must have:

1 the following statement in the email to briefs:

"This Brief has been cleared by .... (name) ....., FAS/Division or AS/Branch/Division *for transmittal to the Minister's Office."*

2 All attachments amalgamated into the briefing document except for:
- healthcomms material (ie speeches, media releases etc)
- pdf documents or other strange formats that won't paste easily into a word document.

***Please note this Briefing should be prepared on the Briefing Template which is accessible via New Office Document, My Templates, PARLIAMENTARY ***

MEETING BRIEF REQUEST FORM

MINISTER Ley
MEETING BRIEF: Australian Dental Industry Advisory Council meeting

DUE IN MO: COB 10 June ADVISER: Adam Wyldeck

Meeting Date: 16 June
Start Time: 11.30am
End Time:
Description:

Will this meeting be held in the Parliament House office? No

If the meeting is held at Parliament House the action area is not required to provide any further information for the venue.

If no,
Address: Dining Rooms, APH

Person/organisation meeting with :
Organisation contact person:
Names of expected attendees:
Purpose of meeting:
Likely issues that may be raised at the meeting:
Other issues:

General background to include:

- organisation history
- Funding provided to organisation (inclusive of whether organisation has recently sought funding)
- Bio of people being met
- Current / contentious issues
- Any other information that may be of relevance

The Department may contact the organisation directly unless instructed not do so.

Will the Minister be represented? No
- If yes, name of Representative:

Has the Department already been contacted by the MO? No
- If yes, name of Departmental officer:

From: Howard, Jenny (S. Ley, MP) [mailto:Jenny.Howard@aph.gov.au]
Sent: Thursday, 2 April 2015 11:24 AM
To: Minister Ley DLO
Subject: FW: Australian Dental Industry Advisory Council meeting [SEC=No Protective Marking]

For brief purposes – I will send additional info from ADIA three weeks prior to the meeting ☺

From: Belinda Bourke - ADIA [mailto:belinda.bourke@adia.org.au]
Sent: Thursday, 2 April 2015 11:13 AM
To: Howard, Jenny (S. Ley, MP)
Subject: RE: Australian Dental Industry Advisory Council meeting

Dear Jenny

Thank you for your email. We look forward to meeting the Hon Sussan Ley MP at 11:30am on Tuesday, 16 June 2015. The meeting will be held in Private Dining Room 3.

Approximately three weeks before the meeting ADIA will forward a briefing note with key discussion points and a profile of those attending.

If I can be of assistance please do not hesitate to contact me at your convenience.

Regards

Belinda

Belinda Bourke
Membership Services Officer ▪ Australian Dental Industry Association

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t: 1300 943 094 ▪ f: 1300 943 794 ▪ m: 0400 300 297
e: belinda.bourke@adia.org.au ▪ www.adia.org.au

From: Howard, Jenny (S. Ley, MP) [mailto:Jenny.Howard@aph.gov.au]
Sent: Thursday, 2 April 2015 10:15 AM
To: Belinda Bourke - ADIA
Subject: Australian Dental Industry Advisory Council meeting

Good morning

I refer to your invitation to the Minister for Health the Hon Sussan Ley MP to meet with the Council on Tuesday 16 June in Parliament and advise that the Minister would be available at 11.30 am on that day.

Please advise if this is suitable to the Council.

Kind regards
Jenny

Jenny Howard, Executive Assistant
THE HON SUSSAN LEY MP
Minister for Health | Minister for Sport
Albury 02 60213264 | **Canberra** 0262 777220 | **E** jenny.howard@aph.gov.au
PO Box 672 | 517 Kiewa Street | Albury | NSW 2640 | www.sussanley.com

Thank you

Regards

David Fortey
Parliamentary Systems Support Section
Ministerial and Parliamentary Support Branch
Portfolio Strategies Division
ph: (02) 6289 5140