

[REDACTED]

From: MASRI, George
Sent: Thursday, 10 May 2018 11:12 AM
To: SKERRITT, John
Cc: [REDACTED] MCLAY, Nicole [REDACTED]
Subject: FW: Letter to [REDACTED] from Adj Prof Skerritt [SEC=UNCLASSIFIED]
Attachments: [D18-10525100] Dep Sec letter to ADIA - RIS for Class I fee.tr5; Dep Sec letter to ADIA - RIS for Class I fee.DOCX

Importance: High

Follow Up Flag: Follow up
Flag Status: Flagged

John – see attached letter which has been cleared by Nicole.
Regards George

From: MCLAY, Nicole
Sent: Thursday, 10 May 2018 10:44 AM
To: MASRI, George
Cc: [REDACTED]
Subject: FW: Letter to [REDACTED] from Adj Prof Skerritt [SEC=UNCLASSIFIED]
Importance: High

Hi George
Could you please submit this to John now.

P.S. please remember to trim workflow documents to me for my clearance as the new EA Corro approach. Outlook is fraught with danger.
Thanks
N

Nicole McLay
A/g First Assistant Secretary, Regulatory Practice and Support



Health Products Regulation Group
Australian Government Department of Health

[REDACTED]

PO Box 100, Canberra ACT 2601, Australia

The Department of Health acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

From: MASRI, George
Sent: Wednesday, 9 May 2018 3:55 PM
To: MCLAY, Nicole
Subject: FW: Letter to [REDACTED] from Adj Prof Skerritt [SEC=UNCLASSIFIED]
Importance: High

Nicole – some minor changes following discussion.

G

From: MASRI, George
Sent: Wednesday, 9 May 2018 3:19 PM
To: MCLAY, Nicole
Cc: [REDACTED]
Subject: FW: Letter to [REDACTED] from Adj Prof Skerritt [SEC=UNCLASSIFIED]
Importance: High

Nicole – this morning [REDACTED] and I met with John to discuss approach to ADIA's letter to John re the RIS. Attached is draft response for John's consideration.

Happy to discuss.

G

From: SKERRITT, John
Sent: Tuesday, 8 May 2018 9:54 AM
To: MCLAY, Nicole; MASRI, George
Subject: FW: Letter to [REDACTED] from Adj Prof Skerritt [SEC=UNCLASSIFIED]

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

Deputy Secretary for Health Products Regulation
Department of Health

(The Health Products Regulation Group comprises the Therapeutic Goods Administration and the Office of Drug Control)

PO Box 100 Woden ACT 2606 Australia
[REDACTED]

From: [REDACTED] - ADIA [REDACTED]
Sent: Tuesday, 8 May 2018 9:51 AM
To: SKERRITT, John
Cc: [REDACTED]
Subject: RE: Letter to [REDACTED] from Adj Prof Skerritt [SEC=UNCLASSIFIED]

Dear John

Thanks for your email.

As set out in earlier representations to the Therapeutic Goods Administration (TGA), there had been an expectation that in accordance with the TGA's public consultation guidelines the proposal to adjust fees by this amount would have been subject to a Regulatory Impact Statement (RIS). This would have been the precursor to public consultation on the proposals.

It's in that context that ADIA is seeking that the introduction be delayed – so that the RIS can be prepared and published for review. This is also the question that's been unanswered – why did the TGA set aside its own commitments to industry without any forewarning that this would be the case?

Regards

[REDACTED]

■ Australian Dental Industry Association



National Office: GPO Box 960, Sydney, NSW, 2001 Australia
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t: ■ f: ■ twitter: ■
e: ■ www.adia.org.au



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From: ■ **On Behalf Of** SKERRITT, John
Sent: Tuesday, 8 May 2018 9:27 AM
To: ■ - ADIA
Subject: Letter to ■ from Adj Prof Skerritt [SEC=UNCLASSIFIED]

Good morning ■

On behalf of Adj Prof John Skerritt, please see a response to your letter dated May 1.

Kind regards

■

to Adj Prof John Skerritt – Deputy Secretary
to Adj Prof Tim Greenaway – Chief Medical Adviser

Health Products Regulation Group
Australian Government Department of Health

Location: Symonston G.G.08

PO Box 100, Woden ACT 2606, Australia

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Australian Government

Department of Health

Deputy Secretary



Australian Dental Industry Association
GPO Box 960
Sydney NSW 2001

Our Reference: D18-10525100

TGA application fee – Class I medical devices

Dear 

Thank you for your further letter of 7 May 2018 regarding the introduction of an application fee by the Therapeutic Goods Administration for inclusion of Class I medical devices in the Australian Register of Therapeutic Goods (ARTG) from 1 July 2018. You have stated that the TGA's position not to prepare a Regulatory Impact Statement (RIS) for this proposal is inconsistent with the position on public consultation stated on the TGA website.

The information on the TGA website was also of surprise to me. Neither I nor any staff I have consulted have been able to determine who authored or approved the posting of this information to the TGA website; it certainly is not TGA/departmental policy. We have long established processes for approving web publication by members of our senior executive but over the last few days I have been unable to determine what happened here. The information is incorrect and actually inconsistent with advice we have had from the Office of Best Practice Regulation (OBPR). The purported requirement that you have quoted is not OBPR policy. My apologies for publication of misleading information but because it was misleading I personally asked that the website be updated immediately to avoid any further confusion.

Under the Australian Government's guide to regulation direct financial costs such as the fees and charges attached to a regulation are excluded from the Regulatory Burden Measurement Framework. Accordingly, the TGA does not usually prepare a Regulation Impact Statement (RIS) for amendments to fees and charges for therapeutic goods and manufacturing licences. Activity-based costing is the well-established mechanism for setting fees and charges, and a comprehensive targeted communication strategy our well-established consultation approach.

As we have previously discussed, the fee has been costed to cover the pre-market staff and IT costs of managing class I device listing and preserving the integrity of the list of class I devices. It would be unlawful for this activity to cover post-market costs or past incurred costs; sadly, in the absence of a class I device inclusion fee in the past we have had to (inappropriately) resource class I listing work from other cost-recovered revenue sources.

The proposed fee is being set in accordance with the [Australian Government Cost Recovery Guidelines](#) (CRGs). As required by the CRGs the TGA's cost recovery implementation statement (CRIS) is being updated and will be published on our website.

As outlined in our earlier response on this matter, and consistent with our long standing practice, we undertook comprehensive targeted consultation by engaging with peak therapeutic industry bodies regarding the introduction of the fee. AS you have acknowledged TGA first raised this proposal (with an indicative fee of about \$600) at the industry bilateral meetings held in February 2017. This was about 14 months ago, when other fees and charges proposals for 2017-18 were discussed. At the December 2017 bilateral meeting we advised that while the fee, for implementation from 1 July 2018, was yet to be finalised, the current fees for similar applications were higher and the class I device fee would be lower than these fees. These included \$1,000 - \$1,290 for inclusion of other types of medical devices and \$800 for listing of a complementary medicine. The final fee of \$530 was discussed at bilateral meetings held in February 2018 and is actually somewhat less than the indicative fees flagged on the two previous occasions.

I trust this information is useful to you and your member companies.

Yours sincerely

Adj. Professor John Skerritt
Health Products Regulation Group

10 May 2018