[redacted]

From: MASRI, George
Sent: Wednesday, 9 May 2018 2:53 PM
To: [redacted]
Cc:
Subject: RE: Letter to [redacted] from Adj Prof Skerritt [SEC=UNCLASSIFIED]

Thanks all – I will accept the changes and send to Nicole.
G

From: [redacted]
Sent: Wednesday, 9 May 2018 2:33 PM
To: MASRI, George; [redacted]
Cc: [redacted]
Subject: RE: Letter to [redacted] from Adj Prof Skerritt [SEC=UNCLASSIFIED]

Dear George

We have amended based on discussion between [redacted] and myself (shown in tracked changes). [redacted] highlighted that the "well-established" practice is accepting activity-based costing as the mechanism for determining fees and charge.

[redacted]
Reform Coordination and Support
Regulatory Services and Improvement Branch
[redacted]
Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: MASRI, George
Sent: Wednesday, 9 May 2018 1:26 PM
To: [redacted]
Cc:
Subject: RE: Letter to [redacted] from Adj Prof Skerritt [SEC=UNCLASSIFIED]

Thanks – I have had a look and made a couple of minor changes and subject to [redacted] response to [redacted] comment we should be OK to send to John via Nicole.

G

From: [redacted]
Sent: Wednesday, 9 May 2018 1:04 PM
To: [redacted]
Cc: MASRI, George; [redacted]
Subject: RE: Letter to [redacted] from Adj Prof Skerritt [SEC=UNCLASSIFIED]

Thank you [redacted] and [redacted]

I have made some minor changes and have a comment. Can I pl have your view on this?

This is now in TRIM.

Happy to discuss.

Thanks
[redacted]

D18-10525100
Kind Regards

[redacted]
Regulatory Pricing & Decision Review
Regulatory Practice & Support

Phone: [redacted]
Email: [redacted]

Health Products Regulation Group
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [redacted]
Sent: Wednesday, 9 May 2018 12:34 PM
To: [redacted]
Cc: MASRI, George; [redacted]
Subject: RE: Letter to [redacted] from Adj Prof Skerritt [SEC=UNCLASSIFIED]

Dear [redacted] and [redacted]

I have inserted [redacted] input and made a few minor changes to the letter.
As discussed with John, potentially we could include the following:

Under the Australian Government's guide to regulation there is no regulatory impact associated with change to this type of fee. Direct financial costs such as the charges attached to a regulation are excluded from the Regulatory Burden Measurement Framework.

[redacted] advice is:

However, whilst the cost is excluded from the RBM framework and are not required to be considered in a regulatory costing some of them may be considered in A RIS depending the significant of that RIS.

[redacted]
Reform Coordination and Support
Regulatory Services and Improvement Branch

[redacted]

Therapeutic Goods Administration
Department of Health

PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: [redacted]
Sent: Wednesday, 9 May 2018 11:53 AM
To: [redacted]
Cc: MASRI, George; [redacted]
Subject: FW: Letter to [redacted] from Adj Prof Skerritt [SEC=UNCLASSIFIED]

HI [redacted] and [redacted]

Here is the draft response which has placeholders for RIS information for you to add. I haven't yet saved this in TRIM.

Happy to discuss.

Regards
[redacted]

Kind Regards

[redacted]
Regulatory Pricing & Decision Review
Regulatory Practice & Support

Phone [redacted]
Email: [redacted]

Health Products Regulation Group
Department of Health
PO Box 100
Woden ACT 2606 Australia
www.tga.gov.au

From: MASRI, George
Sent: Tuesday, 8 May 2018 6:12 PM
To: [redacted]
Subject: FW: Letter to [redacted] from Adj Prof Skerritt [SEC=UNCLASSIFIED]

Just spoke to Nicole who advised that John would like to respond to [redacted] tomorrow. Can we get something for me to look at in the morning, noting that we need clarification re OBPR advice on the RIS.
G

From: SKERRITT, John
Sent: Tuesday, 8 May 2018 9:54 AM
To: MCLAY, Nicole; MASRI, George
Subject: FW: Letter to Mr Troy Williams 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]

[redacted] ■ Australian Dental Industry Association

ADIA

National Office: GPO Box 960, Sydney, NSW, 2001 Australia
Government Affairs: GPO Box 1, Canberra, ACT, 2601
t: [redacted] ■ f: [redacted] ■ twitter: [redacted]
e: [redacted] ■ www.adia.org.au

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

Good morning Mr Williams

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

Kind regards

[redacted]

[redacted]

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

Health Products Regulation Group
Australian Government Department of Health
[redacted]
Location: [redacted]

PO Box 100, Woden ACT 2606, Australia

Australian Government

Department of Health

Deputy Secretary

[redacted]
Australian Dental Industry Association
GPO Box 960
Sydney NSW 2001

Our Reference: D18-10525100

TGA application fee – Class I medical devices

Dear [redacted]

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.

Phone: (02) 6232 8200 **Email:** John.Skerritt@health.gov.au
PO Box 100 Woden ACT 2606 - **www.health.gov.au**

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