[redacted]

From: MASRI, George
Sent: Monday, 7 May 2018 5:53 PM
To: [redacted]
Cc: MCLAY, Nicole
Subject: FW: TGA Fee Proposal - RIS Requirement [SEC=UNCLASSIFIED]
Attachments: 11.11.14L - TGA, RIS Requirement for Class 1 fee.pdf

Importance: High

Follow Up Flag: Follow up
Flag Status: Flagged

FYI
G

From: [redacted] ADIA [redacted]
Sent: Monday, 7 May 2018 5:50 PM
To: SKERRITT, John
Cc: Con Sideris; MASRI, George
Subject: TGA Fee Proposal - RIS Requirement [SEC=No Protective Marking]
Importance: High

Dear John

Having discussed the matter internally I believe I have identified the challenges between industry's expectations and the Therapeutic Goods Administration's (TGA) approach. The attached is self-explanatory.

Regards

[redacted]

[redacted]
[redacted] ■ Australian Dental Industry Association

ADIA
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Australian Chamber of Commerce and Industry Member

Australian Dental Industry Association | ADIA

Ref: 11.11.14L — 7 May 2018

Adj. Prof. John Skerritt FTSE FIPAA(Vic)
Deputy Secretary – Health Products Regulation Group
Department of Health
PO Box 100
WODEN ACT 2606

Dear Professor Skerrit

RE: TGA Application Fee – Class 1 medical devices

The Australian Dental Industry Association (ADIA) refers to previous correspondence with the Therapeutic Goods Administration (TGA) concerning the proposal, from 1 July 2018, to impose a fee of $530 to place products on the Australian Register of Therapeutic Goods (ARTG). The TGA has advised that it will not prepare a Regulatory Impact Statement (RIS) on this proposal; however, this approach is inconsistent with the TGA's stated position with regards to public consultation.

The TGA has, in accordance with guidance published by the Office of Best Practice Regulation (OBPR), made available its consultation protocols on its website. The TGA has published its approach to consultation (refer attached) which provides clear and definitive guidelines on consultation with regards to fees and charges. Your attention is drawn to the following statement

> *Changes to fees and charges are documented in a cost recovery implementation statement (CRIS) which is published on the TGA website. Additionally, where fees and charges are proposed to increase at a rate greater than indexation, a RIS will be considered and prepared and if required a cost recovery impact statement prepared.*
>
> 'About Consultations' (https://www.tga.gov.au/about-consultations)
> Therapeutic Goods Administration, 24 February 2016

In this context, the proposal for the TGA to increase the Class 1 application fee from $0 to $530 can be reasonably stated to "increase at a rate greater than indexation". Thus, in accordance with the TGA's published process to consultations, a RIS is required. This has not been prepared.

ADIA has previously stated that the TGA's proposal merits public review, a request that is in accordance with the TGA's stated position. ADIA therefore again requests that the proposal to introduce a Class 1 application fee be withdrawn from Ministerial consideration and that the RIS be prepared, and submitted to public consultation.

We look forward to your response to this matter.

[redacted]

Australian Government
Department of Health
Therapeutic Goods Administration

About consultations

24 February 2016

We conduct consultations as part of our broader stakeholder engagement (http://www.health.gov.au/internet/main/publishing.nsf/Content/stake-frame) work. Some activities we consult on include:

- Changes to regulatory requirements or practices
- Reviews of business processes
- Reviews of standards or guidelines
- TGA fees and charges

For some change processes, such as an amendment to the *Therapeutic Goods Act 1989* (the Act) or to the Therapeutic Goods Regulations 1990 (the TG Regulations) or the Therapeutic Goods (Medical Devices) Regulations 2002 (the MD Regulations), a consultation process is required in advance of a decision. The consultation process may be part of a regulation impact statement (http://www.dpmc.gov.au/office-best-practice-regulation/regulation-impact-statements) (RIS) or it can be used to inform a RIS that is developed after the feedback from the process has demonstrated a need for change.

For other, less significant changes we may not be required to conduct a formal consultation, but may do so because of the value of the feedback received.

Changes to regulatory requirements or practices

Changes to regulatory requirements and practices can require a significant investment of time and resources, and may require guidelines for external stakeholders and/or development of procedures and training for internal stakeholders before the changes can be fully implemented.

In the case of amendments to the Act, these must go through a full Parliamentary approval process (http://www.peo.gov.au/quick-answers/bills-and-law-qa.html) that involves, at a minimum, three readings in the House of Representatives and another three in the Senate. The entire process of developing the policy, preparing the amendments and consideration by Parliament, can take more than two years, and transition periods may apply before the changes come into effect.

Amendments to the TG Regulations and MD Regulations do not need to go through the full parliamentary process, but they do require ministerial and Executive Council approval. They are tabled in each House of Parliament to provide the opportunity for members and senators to consider and disallow (reject) them.

For a detailed analysis of the regulatory change process, see *Regulatory change: How the TGA legislation and guidelines are amended (//www.tga.gov.au/publication/regulatory-change-how-tga-legislation-and-guidelines-are-amended)*, or refer to the *Legislation Handbook (http://www.dpmc.gov.au/pmc/publication/legislation-handbook)* provided by the Department of Prime Minister and Cabinet.

Reviews of business processes

The TGA sometimes reviews the business processes that are in place to administer various regulatory activities to:

- ensure that they are operating efficiently
- ensure timely approval of therapeutic goods for use in Australia
- minimise the administrative burden for industry.

Reviews of standards or guidance

The TGA reviews its guidance documents as needed to ensure that they are adapted to include new scientific developments and emerging community expectations, as well as to reflect changes in international standards or international harmonisation activities.

Information relating to consultation and submission periods for matters relating to the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons) are published separately and can be found at scheduling advisory commitees invitations for public comment (//www.tga.gov.au/scheduling-advisory-committees-invitations-public-comment).

TGA fees and charges

The TGA reviews its budget on an annual basis, and consults through meetings with industry stakeholders on proposed fees and charges for the following financial year.

Changes to fees and charges are documented in a cost recovery implementation statement (CRIS) which is published on the TGA website. Additionally, where fees and charges are proposed to increase at a rate greater than indexation, a RIS will be considered and prepared and if required. a cost recovery impact statement prepared.

How to participate in consultations

Information about our consultation activities is available via different formats, including a dedicated electronic information service (//www.tga.gov.au/tga-consultations-email-list) that notifies subscribers when a new consultation has been publicly released.

There are a number of ways that you can provide feedback to the TGA other than via a formal submission to a consultation.

- Provide direct feedback to the TGA (info@tga.gov.au (mailto:info@tga.gov.au) or 1800 020 653 or by mail to PO Box 100, Woden ACT 2606)
- Ideas for reducing regulatory burden and red tape reduction can be submitted through the Department of Health's Citizen Space Consultation Hub (https://consultations.health.gov.au/)
- Respond to personal correspondence or an invitation
- Participate in forums organised by the TGA on specific issues
- Speak to a TGA staff member at one of our conference booths

Feedback on our consultations

In the annual reports against the *TGA key performance indicators and reporting measures: Regulator Performance Framework (//www.tga.gov.au/tga-key-performance-indicators-and-measures-regulator-performance-framework)*, we will include information about formal consultations completed during the reporting period, including evidence that we have considered submissions, and measures of stakeholder satisfaction with our consultation processes.

Category: Therapeutic Goods Administration (TGA)
Tags: consultations
URL: https://www.tga.gov.au/node/714024 (//www.tga.gov.au/about-consultations)

The Therapeutic Goods Administration is part of the Health Products Regulation Group

Ref: 11.11.14L — 5 March 2018

Mr George Masri
Assistant Secretary
Regulatory Services and Improvement Branch
Department of Health
PO Box 100
WODEN ACT 2606

Dear Mr Masri

RE: TGA Australian Register of Therapeutic Goods – Class 1 Application Fee

As the peak business organisation representing dental product manufacturers and suppliers, the Australian Dental Industry Association (ADIA) tenders this advice with respect to the Therapeutic Goods Administration's (TGA) proposal to implement an application fee for the placement of Class 1 medical devices on the Australian Register of Therapeutic Goods (ARTG).

It is understood that the Australian Government's overarching cost recovery policy as it applies to the TGA is that, where appropriate, non-government recipients of specific government activities should be charged some or all of the costs of those activities. ADIA's response is tendered both in that context and that of the Australian Government's stated position that cost recovery can improve the efficiency, productivity and responsiveness of government activities and accountability for the same.

General Approach To Cost Recovery —

In the context of the TGA's current funding model, ADIA accepts in-principle that an application fee may be levied to recover the costs to the TGA for placing Class 1 medical devices on the ARTG so long as its design and implementation is consistent with the *Australian Government Cost Recovery Guidelines* published by the Department of Finance.

Transparency & Consultation On Cost Calculation —

It is incumbent on the TGA to minimise cost recovery charges through the efficient implementation of cost recovered activities, in the context of the specific policy outcomes and legislation. As is stated in the *Australian Government Cost Recovery Guidelines*, the cost recovery framework is underpinned by three principles that the TGA must apply across all stages of the cost recovery process: Efficiency and effectiveness; transparency and accountability; and stakeholder engagement. ADIA is of the view that

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these principles have not been met particularly as there has been to transparency as to how the fee has been calculated.

To date the TGA's stakeholder engagement has been limited to explaining that, in the TGA's view, it is necessary to recover costs associated with managing the entry of Class I medical devices on the ARTG. The TGA has not tendered advice as to how the proposed $530 annual charge has been calculated.

Resulting Offsets—

The costs to the TGA managing the process of placing Class I medical devices is not new. In circumstances where no charge has been payable to date, it is assumed that this activity has been subsidised by other activities of the TGA for which fees and charges are payable. It is therefore appropriate that the TGA set out how the new revenue it will receive from the new Class I application fee has been used to offset (*i.e.* reduce) fees from these other areas of activity which hitherto been subsidising the cost of placing Class I medical devices on the ARTG.

Adverse Impacts Of Charges —

Initial consultation with industry is that the proposed $530 fee will significantly add to the compliance burden on Small and Medium-size Enterprises (SME) in the dental industry. Preliminary advice is that, over time, the response of business will be to reduce the number, and therefore range, of new dental products into the Australian market.

As set out above, ADIA accepts in-principle that there may be a charge for placing Class I medical devices on the ARTG; however, to date the TGA has not met the expectations of the Australian Government, as set out in the *Australian Government Cost Recovery Guidelines*, in regard to process and transparency. ADIA therefore seeks:

- Documentation setting out how the proposed $530 fee was charged that clearly sets out the cost inputs used in the calculation;
- The number of businesses (*i.e.* sponsors of Class 1 medical devices) that are likely to be impacted by this change and how many of these are SMEs, using the Australian Bureau of Statistics (ABS) definition which is a business that employs fewer than 20 people;
- The revenue that is estimated to be collected in the first year, and subsequent three years, associated with the charge;
- How the additional (new) revenue has been used to off-set (i.e. reduce) fees and charges from other TGA areas of activity which have previously subsidised the cost of managing the TGA Class 1 application activities; and
- The impact of cost recovery on competition, innovation or the financial viability of the businesses that will pay charges.

The last consideration is important where, consistent with the *Australian Government's Cost Recovery Guidelines*, the TGA must seek advice from stakeholders including ADIA and the Medical Technology Association of Australia (MTAA) as to the impact on business. Preliminary advice from ADIA is that the proposed charge of $530 will, in coming years, reduce the range of new Class 1 medical devices available on the Australian market. The natural consequence will be to reduce the commercial viability of businesses that supply dental products and reduce the range of therapeutic products available to healthcare professionals.

If the TGA is to progress with the application fee in the vicinity of $530, ADIA recommends that this be introduced over a span of two years. As the *Australian Government Cost Recovery Guidelines* makes clear, this partial cost recovery, which occurs when less than the full cost of a government activity is recovered, may be appropriate in some circumstances where charges are being 'phased in'.

As the peak business organisation representing manufacturers and suppliers of dental products, ADIA takes this opportunity to acknowledge the commitment of the TGA to engaging with the dental industry on this issue, and broader matters associated with medical device regulation. We look forward to assisting the TGA as it develops this policy and plans for its implementation.

Yours faithfully

[redacted]

Policy & Research Manager

C.C: [redacted] *Office of the Minister for Health*
[redacted] *Medical Technology Association of Australia*