[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

FYI
G

From: [redacted] ADIA [redacted]
Sent: Monday, 7 May 2018 5:50 PM
To: SKERRITT, John
Cc: [redacted] 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] ■ Australian Dental Industry Association

ADIA

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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]

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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)