[redacted]

From: MASRI, George
Sent: Tuesday, 8 May 2018 6:26 PM
To: [redacted]
Subject: FW: Introduction of a fee for inclusion of Class I medical devices [DLM=For-Official-Use-Only]

[redacted] – I assume you have this?
G

From: [redacted]
Sent: Tuesday, 8 May 2018 1:33 PM
To: MASRI, George
Subject: FW: Introduction of a fee for inclusion of Class I medical devices [DLM=For-Official-Use-Only]

Kind Regards

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

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

From: [redacted]
Sent: Tuesday, 10 April 2018 8:41 AM
Subject: Introduction of a fee for inclusion of Class I medical devices [DLM=For-Official-Use-Only]

Good morning [redacted]

I have made enquiries with TGA's regulatory pricing area with regard to OBPR's questions about the introduction of a fee for inclusion of Class I medical devices. This fee change is not part of the MMDR implementation it is part of an industry wide process that is done by the TGA annually. The process considers whether our fees and charges are appropriate and is done in line with the Government's Cost Recovery Guidelines (CRGs). The TGA is required to recover the cost of activities that fall within the scope of the *Therapeutic Goods Act 1989*, including industry regulation.

The current medical devices regulatory framework commenced in 2002 and while a fee has never been charged for the inclusion of a Class I medical device in the Australian Register of Therapeutic Goods (ARTG), there has always been scope under the framework to do so. This is currently the only category of therapeutic good without an entry fee for the ARTG. The absence of a fee for inclusion of Class I medical devices is inconsistent with the CRGs and as such the TGA will introduce a fee of $530 for inclusion of a Class I medical device in the ARTG from 1 July 2018.

Consultation on all therapeutic goods fees and charges for 2018-19 (including the introduction of a fee for inclusion of Class I medical devices was undertaken with key therapeutic industry representative bodies in December 2017 and February/March 2018. Additionally, it was also raised at the February 2017 bilateral meetings and through

other consultative forums, including the Regulatory & Technical Consultative Forum (the 22 February 2018 meeting). No concerns were raised at these forums.

With regard to the best practice regulation requirements it is my understanding that the TGA is not required to prepare a regulatory impact statement for amendments to increase fees and charges for therapeutic goods and manufacturing licences. There is a standing agreement in place between the Office of Best Practice Regulation and the Department of Health removing the need for a preliminary assessment when using the well-established formula used to calculate these amendments (OBPR Reference Number: 14416).

Additionally, since the release of the new CRGs in 2014, the TGA is also not required to prepare a cost recovery impact statement. Instead, a cost recovery implementation statement must be prepared and released on our website before charging begins. As required by the CRGs a cost recovery implementation statement will be prepared prior to the revised fees take effect. It will include further information on the new fee, and it will be published on our website before 1 July 2018.

One peak body has been critical of the TGA for not providing adequate detail of how the proposed fee for inclusion of Class I medical devices was calculated and for not preparing a cost recovery impact statement for noting the impact of the proposed fee on industry, including SMEs. They also consider that the TGA has not provided enough notice before the planned implementation date of 1 July 2018. On 22 March 2018, the TGA wrote to the peak body that the proposed fee of $530 is based on the staffing cost, plus the appropriate corporate allocation under our activity based costing approach.

We note the impact that the one-off additional cost of $530 may have on the sponsors of new class I medical device entries (noting this would not impact existing entries). There will be no additional regulatory impact associated with the fee increases.

We monitor cost recovery for each industry sector, and annual charges for some medical devices were reduced for 2015-16, and for most medical devices again in 2017-18. We will continue to monitor the level of cost recovery against our costs.

Please contact me if you have any further questions.

Kind regard, [redacted]

[redacted] Reform Coordination and Support Section

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Health Products Regulation Group
Australian Government Department of Health

[redacted]

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