

From: MASRI, George
Sent: Thursday, 10 May 2018 4:06 PM
To: SKERRITT, John; MCLAY, Nicole; [REDACTED] DUFFY, Tracey
Subject: FW: TGA Approach To Consultation [SEC=UNCLASSIFIED]

Follow Up Flag: Follow up
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From: [REDACTED] - ADIA [REDACTED]
Date: Thursday, 10 May 2018, 3:51 pm
To: MASRI, George [REDACTED]
Cc: [REDACTED]
Subject: RE: TGA Approach To Consultation [SEC=UNCLASSIFIED]

Dear George

Thanks for your email.

The issue is broader than the simple change to the website context. The Australian Dental Industry Association (ADIA) and other stakeholders were expecting that the Therapeutic Goods Administration (TGA) would adhere to its published consultation protocols.

Having met with the Australian National Audit Office (ANAO) yesterday, ADIA has a better understanding of what information they are looking for in terms of understanding the TGA's engagement with industry. This serves as a good example, it gives rise to strong concerns about process if TGA consultation protocols can be amended without notice and stakeholders find themselves unable to rely on the TGA's published statements.

The TGA's act of altering the website text after it has been identified the protocol set out in that text had been breached is not a good look – it certainly raised a few eyebrows at today's meetings in parliament house. It's an act that's certainly going to be assessed in more detail.

As requested, ADIA requests that the recommendation be withdrawn from Ministerial consideration so that the RIS can be prepared and subjected to public review. With that commitment it would be possible to move-on.

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



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From: MASRI, George

Sent: Thursday, 10 May 2018 3:10 PM

To: [REDACTED]

Cc: [REDACTED]

Subject: RE: TGA Approach To Consultation [SEC=UNCLASSIFIED]

[REDACTED] – when this was brought to John's attention (for the first time via your letter) he asked for the text to be removed as it was inconsistent with our practice and that the website needed to be updated to avoid any further confusion.

John will be writing to you soon in response to your letter.

Regards George

From: [REDACTED] - ADIA [REDACTED]

Sent: Thursday, 10 May 2018 12:55 PM

To: MASRI, George

Cc: [REDACTED]

Subject: TGA Approach To Consultation [SEC=No Protective Marking]

Importance: High

Dear George

The Australian Dental Industry Association (ADIA) notes the change in the Therapeutic Goods Administration (TGA) public statements on consultations as referenced on the following page on the website:

www.tga.gov.au/about-consultations

It is noted that the following text has been removed in the version published on 8 May 2018:

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.

Are you able to elaborate on the decision-making process that lead to this change?

Thanks and regards

[REDACTED]

[REDACTED] ■ Australian Dental Industry Association



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