

NATERA, Julian

From: Vinod Mahajan <Vinod.Mahajan@tga.gov.au>
Sent: Thursday, 9 April 2015 12:27 PM
Subject: FW: ACTION: Follow-up action: MS15-000733 Low Value Turnover Scheme - Additional Questions [DLM=For-Official-Use-Only]

Importance: High

Hi Phill.

Could you please make the suggested changes to the RIS.

I will put together responses to comments on MinSub for Nicole's clearance.

Regards

Vinod

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From: Tara Condon **On Behalf Of** TGA Parliamentary
Sent: Thursday, 9 April 2015 12:10 PM
To: Nicole McLay
Cc: Vinod Mahajan
Subject: ACTION: Follow-up action: MS15-000733 Low Value Turnover Scheme - Additional Questions [DLM=For-Official-Use-Only]
Importance: High

Good afternoon Nicole, Vinod

Please see the below additional questions on MS15-000733 as asked by the AMO.

If we could kindly ask that the responses are forwarded to Parliamentary at your earliest convenience, it would be appreciated.

Thank you
Tara

TGA Parliamentary
Lisa Selems / Katie Wineland / Tara Condon
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From: Rocks Martin [<mailto:Martin.Rocks@health.gov.au>] **On Behalf Of** Minister Nash_DLO

Sent: Thursday, 9 April 2015 12:03 PM

To: TGA Parliamentary

Subject: Follow-up action: MS15-000733 Low Value Turnover Scheme - Additional Questions [DLM=For-Official-Use-Only]

Team – please note comments below from MO to the Minsub (coincidentally it has come back out this morning).

If we can obtain this additional information when possible we can resub to the Minister.

Many thanks

Martin

MINSUB QUESTIONS

In general, a very well-written Minsub and RIS. Please pass on the Minister's thanks to the TGA.

- 1) Minsub pg 4 under Sensitivity:
 - a. Please provide further rationale for publishing the particulars of LVT exempt and waived entries on the TGA website. At first glance, this initiative appears to contradict the TGA's principles of treating applications as commercial-in-confidence and it's not clear why this information is useful to consumers and/or health care professionals.
 - b. Please provide a description of the particulars the TGA intends to publish.
 - c. What feedback has the TGA received from sponsors on this suggestion?
 - d. What level of TGA resources will be required to maintain and publish this information? Does this detract from the administrative efficiencies to be gained by the Review of the LVT?
 - e. If this is indeed necessary, perhaps it would be better to publish aggregate rather than product specific data.
- 2) Minsub pg 3 under 'Design of the new scheme' - What is the fee for sponsors to apply to the Secretary for reinstatement of the exemption(s) for ARTG entries?
- 3) Minsub pg 3 last dot point – What decision-making criteria will the Secretary use to a) determine if a sponsor is genuine in its claim that it is not commercially viable to supply the product
- 4) Minsub pg 4 under Annual charges- The minsub states that around 74% of the current LVT exempted entries will be exempt under the new scheme. Later in the paragraph it states the TGA has assumed a withdrawal rate of 50% of currently exempted entries which will no longer qualify for an exemption. Does this indicate the TGA is expecting half (or 50%) of the 26% of products that are no longer exempt to be withdrawn from the market?
- 5) Minsub pg 5 under Consultations – Please provide a copy of the ADIA letter to the AMO (Att: Emma Wood). Did the TGA respond to the letter? If so, please provide a copy or summary of the response.

RIS FEEDBACK

- 1) Contents page – The font for the main headings appears to be larger than necessary. The TGA may wish to adjust the font size.
- 2) Pg 16 – The heading 'Why is government action needed' seems a little out of context. Can we change this to "Why is policy change needed?" and edit the first sentence to say "Policy change is needed because..."
- 3) Pg 22 - Last dot point is missing a full stop.
- 4) Pg 24 - Second dot point – 20 sponsors will be selected for an audit. This isn't a large percentage of the total sponsors expected to apply. Would it be wiser not to publish this figure and simply state and audit program will be in place?
- 5) Pg 29 paragraph four – suggest replacing "is an inexact science" with "is complex"