RIS/504019

NATERA, Julian

From: Phillip Cooley <Phillip.Cooley@tga.gov.au>
Sent: Tuesday, 12 May 2015 3:32 PM
Subject: RE: URGENT response: MC15-007924 [SEC=UNCLASSIFIED]

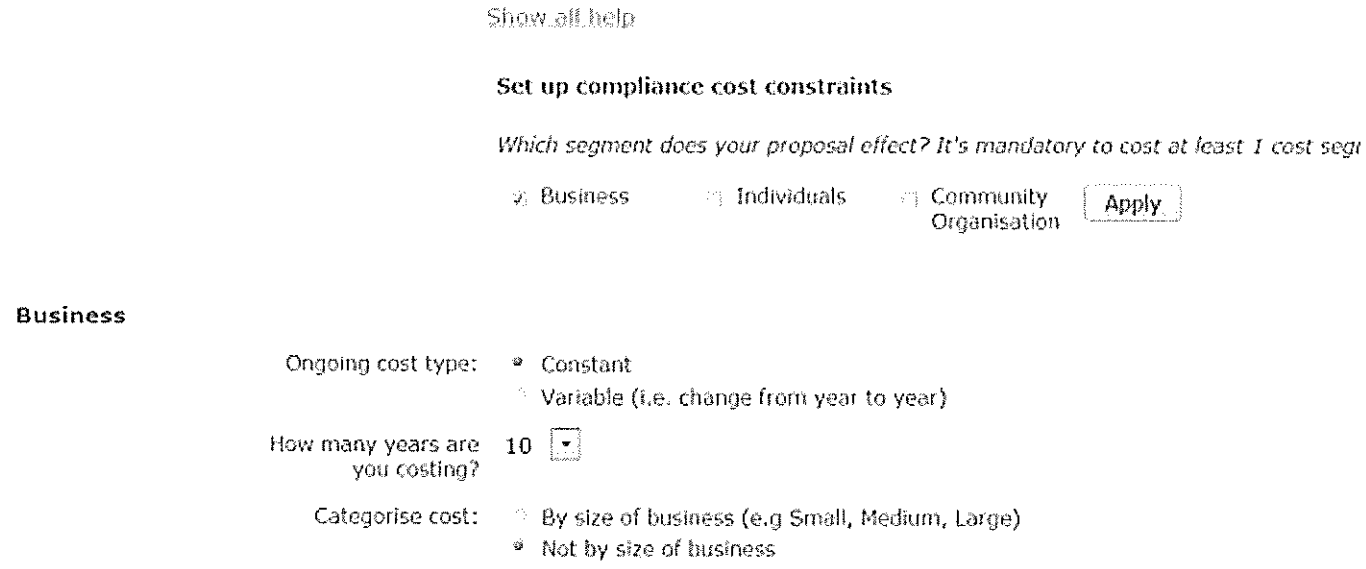
Vinod

No. The issue came up during development of the consultation paper but no hard analysis of ACE on small business was undertaken at that time as we had not identified a preferred pathway for the new scheme until after the consultation.

The subsequent RBM costing (for RIS) was calculated on the basis of the actual number of sponsors/entries subject to the current LVT who would be affected by a change to an ACE scheme – again these include small, medium and large business sponsors.

- The stand-alone small business impact question was not addressed in the RBM analysis as a No Supply or $0 turnover scheme were (already) identified as the preferred options to deregulate the LVT scheme.

- I recall us discussing and agreeing that the impact of the new scheme would be assessed at the "**Business**" and "**Not by size of business**" level. A quick revisit of the RBM compliance cost constraints confirms as much (detail below).



On the plus side, we did prepare numerous sample analyses across the different sectors for ACE impacts however these were for specified sponsors who were being consulted in each of those sectors – they were not specifically small business (only) sponsors.

Regards

Phillip Cooley
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Regulatory Business Services Branch

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From: Vinod Mahajan
Sent: Tuesday, 12 May 2015 2:50 PM
To: Phillip Cooley
Subject: FW: URGENT response: MC15-007924 [SEC=UNCLASSIFIED]

Hi Phill,

As part of RIS costing, did we do an impact analysis on small business as per Nicole email below?

Regards

Vinod

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From: Nicole McLay
Sent: Monday, 11 May 2015 5:07 PM
To: Vinod Mahajan; Phillip Cooley
Cc: Joe Menegazzo
Subject: FW: URGENT response: MC15-007924 [SEC=UNCLASSIFIED]

Hi Vinod and Phillip

Did you at one stage do some analysis on small business using a certain number of products as the indicator of sponsor size, and the impact of change from LVT to ACE? Taking into account the small businesses not claiming LVT? There was also some work you did for the letters back to ADIA.
I think we need to make a point in the talking points that TG regulation is cost recovered and annual charges are the means by which we recover post market monitoring and compliance activity.
There is cross subsidisation in the current scheme that needs to be addressed.
Note - There is a short response time on this request, so we will need to prioritise it in the ACE work.

Joe – I thought that our significant discrepancy in the CRISs was comp meds, but is it right that devices post market costs 8.4m and we're recovering 20m?
Do the financial forecasts in the CRISs take into account the charge reductions of 5 and 23% (please include).
Why then is device annual charge revenue increasing?

Sorry, while we're on CRISs, what/who is the source of the volumes and how have they been verified?

Thanks
Nicole

From: Katherine (Katie) Wineland **On Behalf Of** TGA Parliamentary
Sent: Monday, 11 May 2015 4:50 PM
To: Nicole McLay; Vinod Mahajan
Subject: URGENT response: MC15-007924 [SEC=UNCLASSIFIED]

Good afternoon Nicole & Vinod

Please find attached a request for response and talking points.

Correspondence number – MC15-007924

Marked for ministerial response.

Due to Parliamentary, FAS cleared – COB Friday 15 May 2015.
I am sorry about this short turnaround, but we only received it this afternoon.

Notes:
PDF also at R15/389968

They have requested a response as well as talking points for a meeting that the Assistant Minister will have with ADIA.

Many thanks
Katie

TGA Parliamentary
Lisa Selems / Katie Wineland / Tara Condon
Business Capability and Committee Support
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