

GUNAWARDENA, Shan

From: LISSON, Kylie
Sent: Monday, 7 December 2015 11:50 AM
To: GUNAWARDENA, Shan
Cc: TGA FOI
Subject: FW: Request to access a document - R15/419917 [SEC=UNCLASSIFIED]

2nd attempt...

Kylie Lisson

Executive Assistant to
Ms Judy Develin
Assistant Secretary
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
Tel : (02) 6232 8034

From: LISSON, Kylie
Sent: Monday, 7 December 2015 11:48 AM
To: GUNAWARDENA, Shan
Cc: TGA FOI
Subject: RE: Request to access a document - R15/419917 [SEC=UNCLASSIFIED]

As discussed...

Kylie Lisson

Executive Assistant to
Ms Judy Develin
Assistant Secretary
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
Tel : (02) 6232 8034

From: John Skeritt [<mailto:John.Skeritt@tga.gov.au>]
Sent: Thursday, 14 May 2015 11:36 AM
Subject: RE: Response to ADIA - ACE scheme [SEC=UNCLASSIFIED]

This looks good. Apart from talking about equity can we say

1. That the additional 5 % reduction in medical device changes was not taken into account in calculating the impact on the 5 sponsors (please check my letter first though !) as this was only confirmed recently and
2. Emphasise that the analysis of additional costs to the 5 sponsors did not include the cut in 1. And draw an even more direct line of sight to the ability of sponsors to claim a public health exemption or remove poorly selling products from the register. Have we also mentioned the exemption granted for products getting LVT over the last two years ?
3. Finish up by saying our modelling shows that the costs will be lower for the majority of small businesses. (a vague mention of equity could be seen as cost shifting)

John

Adjunct Prof John Skeritt FTSE FIPAA (Vic)
National Manager, Therapeutic Goods Administration

Deputy Secretary, Department of Health

PO Box 100 Woden ACT 2606 Australia
Phone: (02) 6232 8200 Fax: (02) 6203 1265
Email: John.Skerritt@tga.gov.au

From: Nicole McLay
Sent: Thursday, 14 May 2015 11:05 AM
To: John Skerritt
Cc: Judy Develin; Lee Wah; Vinod Mahajan
Subject: Response to ADIA - ACE scheme [SEC=UNCLASSIFIED]

Hi John

The following letter and talking points will be sent to you through EA Corro. This advance copy is in case you want it for your meeting with Assistant Minister Nash today.

Thanks
Nicole

Nicole McLay FCPA
Assistant Secretary
[Regulatory Business Services](#)

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