

**MAY, Emily**

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**From:** HUDSON, Terrie-Lee on behalf of TGA Media  
**Sent:** Tuesday, 22 December 2015 12:13 PM  
**To:** TGA FOI  
**Subject:** FW: LVT scheme review [SEC=UNCLASSIFIED]

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**From:** Frank Marando **On Behalf Of** GSU PC  
**Sent:** Tuesday, 9 June 2015 3:13 PM  
**To:** News  
**Subject:** RE: LVT scheme review [SEC=UNCLASSIFIED]

Hi Neil,

Tony Gill has cleared the following response:

- The proposal to replace the current low value turnover (LVT) scheme with the annual charge exemption (ACE) scheme are set out in the Therapeutic Goods Legislation Amendment (Annual Charges Exemption) Regulation 2015, which was approved by the Governor-General on 28 May 2015 and commences on 1 July 2015.
- The Regulation Impact Statement (RIS) identifies an annual saving to industry of \$3 million in administrative costs and \$2.4 million in LVT application fees. It is acknowledged that the replacement of the LVT scheme with the new ACE scheme will have varying impacts on individual sponsors, but overall would achieve a benefit to industry. The TGA is not aiming to generate more annual charge revenue from this change, and will have a reduction in revenue of \$2.4 million from the current application fees. The RIS has been cleared by the Office of Best Practice Regulation within the Department of Prime Minister and Cabinet.
- Under the proposed scheme, all products would qualify for an exemption if they were granted LVT exemptions on the basis of \$0 turnover in the last two financial years rather than since their entry on the ARTG. In addition, all new medical devices (including class 1 medical devices) would automatically qualify for the exemption until they commence turnover. This is a significant advantage of the new scheme for class 1 medical device sponsors because they generally don't seek exemption under the current scheme as the LVT application fee of \$155 alone is far more than the annual charge of \$80. In addition, medical device classes IIa and above would benefit from a 5% reduction in annual charges from 1 July 2015.
- There is a new provision in the regulations that allows for waiver of the annual charge if certain criteria are met in relation to public health and financial viability for medicines, Class IIa and above devices and IVDs.
- In view of the above, the proposed scheme simplifies the participation requirements, in particular for small businesses, and will significantly reduce red tape and regulatory burden for industry. The TGA will monitor the impact of the new scheme on the therapeutic goods industry and will cover all sectors.

Thank you.  
Frank

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**From:** BRANCH, Neil [<mailto:Neil.Branch@health.gov.au>] **On Behalf Of** News  
**Sent:** Tuesday, 9 June 2015 1:05 PM  
**To:** GSU PC  
**Cc:** [News@health.gov.au](mailto:News@health.gov.au)  
**Subject:** FW: LVT scheme review [SEC=UNCLASSIFIED]

See below – for suggested response please.

**From:** Michelle Lam [<mailto:michelle.lam@lushmedia.com.au>]  
**Sent:** Tuesday, 9 June 2015 1:04 PM  
**To:** News  
**Subject:** LVT scheme review [SEC=No Protective Marking]

Hi

This is a query for the TGA.

I've been advised by the Australian Dental Industry Association (ADIA), that it has requested the Department of Prime Minister and Cabinet to review what it says is an "incomplete" Regulatory Impact Statement (RIS) produced by the Therapeutic Goods Administration (TGA) in its proposal to get rid of the low value turnover (LVT) scheme.

Is the TGA aware of the review being requested/conducted by the Department of PM&C?

If there is an ongoing review by the Department of PM&C, does it mean the new Annual Charge Exemption (ACE) scheme the TGA plans to implement from July 1 cannot go ahead?

The ADIA claims the TGA ignored its own assessment showed there will be an increase of around 30 per cent in charges for businesses that sell dental products under the new scheme - would the TGA like to respond to that?

My deadline is 3:30pm today. Thanks for your help.

Kind regards,

Michelle.

Michelle Lam

Journalist

Pharma in Focus

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**pharma**   
in focus