

## NATERA, Julian

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**From:** Vinod Mahajan <Vinod.Mahajan@tga.gov.au>  
**Sent:** Friday, 13 February 2015 3:53 PM  
**Subject:** RE: TGA - Low Value Turnover Review [DLM=For-Official-Use-Only]

Thanks John.

This matter has been discussed at length in our workshop meetings and there seemed to be a view that the cost of verifying those entries outweighs the benefit. Moreover, our assessment is that there are not many class 1 devices which have zero turnover because such entries can be included in the Register with ease and without cost. We don't charge an application fees for inclusion of a class 1 device. So why would a sponsor keep a \$0 turnover class 1 devices on the Register?

Having said this, if a sponsor is going to be impacted significantly because of this they have the option to cancel the old entry and include a brand new entry without cost which would be eligible for exemption under the new scheme until that entry commences turnover. The only downside of this will be that the new device entry would have a brand new ARTG # but my understanding is that there is no labelling requirement for devices so this should not have any impact on them. Would this idea sell?

Please let me know if you want us to think more about this.

Regards

Vinod

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**From:** John Skerritt  
**Sent:** Friday, 13 February 2015 3:30 PM  
**To:** Vinod Mahajan; Nicole McLay  
**Cc:** Phillip Cooley  
**Subject:** RE: TGA - Low Value Turnover Review [DLM=For-Official-Use-Only]

Reading into to the comment on class 1 devices and their inability to refer to evidence that they had zero turnover in previous years I think that we will have to think about an approach where some form of declaration can be made by the sponsor. Otherwise they will scream with some justification.  
Ideas ?

John

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**From:** Vinod Mahajan  
**Sent:** Friday, 13 February 2015 3:02:00 PM  
**To:** John Skerritt; Nicole McLay

**Cc:** Phillip Cooley  
**Subject:** RE: TGA - Low Value Turnover Review [DLM=For-Official-Use-Only]

Yes John.

Regards

Vinod

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**From:** John Skerritt  
**Sent:** Friday, 13 February 2015 2:54 PM  
**To:** Vinod Mahajan; Nicole McLay  
**Cc:** Phillip Cooley  
**Subject:** RE: TGA - Low Value Turnover Review [DLM=For-Official-Use-Only]

Vinod

Thanks for this. Will scrutinize closely but just a quick question - did we deduct the current \$155 lvt application fee when we calculated the impact on each product?

John

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**From:** Vinod Mahajan  
**Sent:** Friday, 13 February 2015 2:33:39 PM  
**To:** John Skerritt; Nicole McLay  
**Cc:** Phillip Cooley  
**Subject:** RE: TGA - Low Value Turnover Review [DLM=For-Official-Use-Only]

Good Afternoon John,

Please find below a summary of impact on charges for the 5 ADIA member companies.

Company Name	Current Charges	Proposed Charges	Impact
1. VOCO Australia Pty Ltd	\$8,445	\$23,370	(\$14,925)
2. Dentsply (Australia) Pty Ltd	\$74,830	\$85,810	(\$10,980)
3. City Dental Supplies (T/a Casemate)	\$4,085	\$6,140	(\$2,055)
4. Amalgadent Dental Supplies (Australian) Pty Ltd	\$26,610	\$33,690	(\$7,080)
5. J Wisbey & Assoc Pty Ltd	\$5,980	\$7,260	(\$1,280)
<b>Total</b>	<b>\$119,950</b>	<b>\$156,270</b>	<b>(\$36,320)</b>

As you are aware, we are proposing a reduction of 5% in annual charges for medical devices class II and above which means annual charges for all types of class 1 medical devices will remain unchanged.

Please note that:

- The new class 1 medical devices (other than class 1 measuring and class 1 sterile), entered on the Register after the commencement of the proposed scheme would benefit more under the new model as most devices under this category are not seeking exemptions under the current LVT scheme as the annual charge of \$80 for a class 1 device is less than the \$155 LVT application fees. Given that there would not be any requirement to make an application (or pay application fees) for exemption under the new scheme the new class 1 devices would not incur annual charges until they commence generating turnover. However, downside of the proposal is that the existing class 1 devices, even if they have not had turnover in the past, will not be exempt as they would not meet the primary criterion for transitional entries (at 1 July 2015) that they would have been exempted under the LVT scheme on the basis of \$0 turnover in the last two years before the commencement of the new scheme (i.e. 2013-14 and 2014-15). There could be some sensitivity around this and you may like to draw Minister Nash's attention to this.
- One of the above ADIA members, VOCO, failed to make the LVT application in 2014-15 and paid the full charges. However, in 2013-14 they claimed LVT exemptions for 23 of their 30 Class IIA devices. Therefore, for comparison purposes, we assumed what charges they would have paid in 2014-15 had they made the LVT application in time and compared that with the charges that would become payable under the proposed model.

Please refer to the attached spreadsheet for a detailed analysis. I have also attached a list of products belonging to these companies, as you requested.

Please let me know if you need any further information.

Regards

Vinod

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**From:** John Skerritt  
**Sent:** Thursday, 12 February 2015 11:42 AM  
**To:** Nicole McLay; Vinod Mahajan  
**Subject:** FW: TGA - Low Value Turnover Review

Finally received the list of companies from ADIA. I assume that these are only small companies. Any chance of running the numbers before I see Min Nash on Monday. It would be good to provide the spreadsheet of individual products from each company as we will probably need to discuss whether some products would potentially be seen as unique and critical for public health.

John

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**From:** Troy Williams - ADIA <[troy.williams@adia.org.au](mailto:troy.williams@adia.org.au)>  
**Sent:** Thursday, 12 February 2015 11:10:10 AM  
**To:** John Skerritt  
**Cc:** Elise Mizzi - ADIA  
**Subject:** TGA - Low Value Turnover Review

Dear John

Thanks for agreeing to have the team at the Therapeutic Goods Administration (TGA) review the impact of the proposed changes to the low value turnover scheme.

Five businesses that are members of the Australian Dental Industry Association (ADIA) have agreed to have their fees reviewed in the process and their details are attached. With respect to VOCO there may need to be a study of the prior years as they missed the cut-off if the present years.

If you could let me know the next step that would be appreciated.

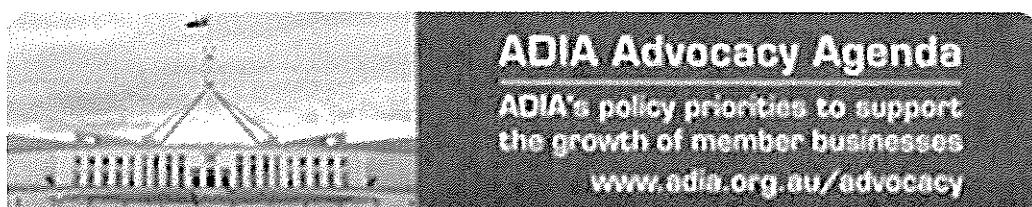
Thanks and regards

Troy

Troy R Williams FAIM MAICD  
Chief Executive Officer ■ Australian Dental Industry Association



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