



## Australian Government

### Department of Health Therapeutic Goods Administration

Mr Troy Williams  
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Australian Dental Industry Association  
GPO Box 960  
Sydney NSW 2001

Our Reference: EAC 426777

Dear Troy

#### **Low value turnover scheme**

Thanks for your letter of 8 January and follow-up email on 12 February. We are glad that ADIA is a strong advocate of reforms to deliver a regulatory framework for dental products that is based on a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden. In this context, ADIA is supportive of reform to the LVT scheme that will reduce the administrative workload of businesses in the dental industry.

My colleagues have now "run the numbers" with the five sponsors you listed, to assess the impact of the proposed changes to the low value turnover scheme. TGA is proposing a reduction of 5% in annual charges for medical devices class of II and above but annual charges for all types of class 1 medical devices will remain unchanged.

Our analysis of the maximum impacts is shown in the table overleaf. However it is important to note:

- **A number of products may be eligible for criteria as an "essential good" for public health and thus be eligible for waiver of fees.** We haven't tried to determine which dental products would qualify as we will be assessing waiver applications on a case by case basis. But I would imagine that a product such as a highly specialised forceps could potentially be eligible.
- Our discussions with other parts of the devices and medicines industry is that they will potentially use the changes to the scheme to identify products that are selling in small quantities, don't particularly fill any specialist niche, and are possibly costing more for the sponsor to support in the market than the profits obtained. **These products would then be withdrawn from the ARTG and also not pay annual charges.** Of course this action would be a commercial decision of the sponsor.
- **New class 1 devices (other than class 1 measuring and class 1 sterile), entered on the Register after the commencement of the proposed scheme would**

- benefit more than at present**, as our data shows that most devices under this category are not currently 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.
- Existing class 1 devices 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). 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 new device entry would have a new ARTG number but as there is no labelling requirement for such devices so this should not have any impact on them.

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>

Note: for comparison purposes, we assumed the charges VOCO 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.

The fact that one of the above ADIA members, VOCO, failed to make the LVT application in 2014-15 and paid the full charges is indicative that the administrative burden of applying for the exemption under this scheme can outweigh the benefits at present. We hear of varying figures, but TGA has often been told that the cost of contracting an independent accountant and the costs of creation and verification of LVT lists are more than \$ 10,000 per sponsor. So taking the potential cost saving of reducing this paperwork plus the other factors listed in the points on the previous page my expectation is that overall at worst it would be cost neutral for these representative member companies.

The sole aim of the proposed changes to the low value turnover scheme is to reduce red tape for business, particularly small business who are currently compelled to submit declarations audited by an independent accountant, and have such declarations submitted by a particular date.

These two requirements are extremely unpopular with many, if not most sponsors and result from inflexibilities in our Act. Unless if we change the Therapeutic Goods Act at this stage, we cannot merely "tweak" the current LVT scheme to remove these requirements. Furthermore, with the government's legislative programme and the nature of the changes that would be required in modifying the Act in this way, changes to the LVT scheme could not be implemented until July 2016 at the earliest, and possibly later. This delay would be unacceptable to many in industry. The proposed introduction of a "no value turnover" scheme means that we can make the changes through regulation and we plan to have them in force by July 1 this year.

If you would like to meet to discuss this analysis and other issues relating to LVT we would be happy to do so.

Yours sincerely



John Skerritt  
National Manager  
16 February 2015