Submission No. 27

Response to TGA Review of the low value turnover exemption scheme

With the main rationales in mind that the LVT scheme needs to be regulated to support small business and annual charge are necessary to fund the TGA’s post market compliance and monitoring function, this response is to support option 2 with some incorporation of options 3 and 4 that favour zero-turnover Register entries and small businesses.

Issues relating to Option 2:

1. Do you support the option of continuing with the LVT scheme in its current form but amended as above? Please provide detail on why you hold this view.

Accept self-declaration from small businesses of the turnover of their product.

thinks the current LVT scheme should be adjusted in a way that it could deliver the original objectives of assisting small business which it did not quite achieve much in the past. This has been observed by the fact that 75% of TGA sponsors have 10 or fewer entries on the register but claim only 3% of total LVT benefit. As such, agrees that flexibility on application of annual charge exemptions should be granted to small business to relieve them from the burden of preparing and submitting an LVT application, making them become the priority and the most major beneficiaries of the LVT scheme.

Provide provision in the Regulations for an extension of the deadline for submitting an LVT exemption application, possibly with a late lodgement fee, or remove the option for extension of the deadline for submitting validation information for new entries in the prior year so that the deadlines for these two processes cannot be confused.

supports the possible change of deadline extension for LVT exemption. The two different deadlines are confusing that it might be easily assumed by the sponsor that extension for LVT exemption application for current entries could be granted which results in compilation of required information has to be done in rush when extension request is rejected.

Remove the annual cap of $15,000 for LVT application fees for greater alignment with the Cost Recovery Guidelines as there are no administrative efficiencies gained on applications with a higher number of products.

The annual cap for LVT application fees is currently a maximum application fee of $15,000 per financial year, even though exemption is sought for more than 100 entries in that financial year. Removal of this annual cap is highly supported, as the LVT fee is not excessive, and extra revenue raised by paying for every LVT product, will contribute to covering the administrative costs of processing, which are currently not being covered by setting a cap.

In addition, all products launched to market requires an equal amount of post market activities. Therefore, it is not appropriate that a Register entry of annual turnover in excess of zero is exempted from annual charge through LVT application fee being capped at $15,000.

2. What do you see as the broader benefits of this option?

With the current scheme, given the cost recovery at the TGA, the LVT benefit (of which 85% is received by large businesses, and 50% is received by the top 20 sponsors) is recovered by cross subsidy by all the sponsors (of which 75% are small businesses) through increasing rates of annual charge. A change to the current scheme (self-declaration from small businesses of turnover of their products) will make small businesses more accessible to the LVT benefit. This option will create a better balance in terms of the beneficiaries of the LVT scheme from predominantly large companies to smaller business sponsors.

Removing the current LVT application cap will also mean that some extra venue may be raised, without incurring extra expenditure in administrative costs to process those LVT applications above 100 products.

By retaining eligibility for annual charge exemptions to Register entries by medium and large companies (i.e. LVT scheme is not just exclusive to small business sponsors as in option 4) would result in more entries remaining on the Register, resulting in a quicker time to market for those products; sponsors create Register entries several months prior to product launch, to get the prelaunch materials together, and if this occurs towards the end of financial year, the product has zero or low turnover of the product, and is therefore benefited by the LVT scheme.

With a combination of the above, LVT scheme will function in a more effective and balance way where it spreads out the benefits across large, medium and small businesses: Large and medium companies (25% of sponsors) contribute to cross subsidy for small business (75% of sponsors) due to their Register entries are LVT exempt regardless of turnover value; small business sponsors (accounting for 26,660 Register entries – assuming each sponsor has 10 entries – which is 36% of total entries) contribute to cross subsidy for large and medium companies (accounting for 47,171 Register entries - 64% of the total entries) who have high LVT exemption proportion of 42% (assuming all 20,027 LVT exemptions in 2012-13 belonged to large and medium companies as small business only obtained 3% of LVT benefit).

3. What do you see as the drawbacks of this option?

There is still a large amount of administrative paperwork to identify LVT turnover of zero and low volume products, and to get this turnover approved by a third party accountant. However, if the turnover is zero, representing no supply to the Australian market (see below), then approval by a third party accountant could be waivered.

Submission No. 27

4. If you could improve the way the LVT scheme operates, what changes would you introduce?

Refining eligibility of LVT exemption to zero-turnover Register entries for those sponsors who are not small business

Not until a product is placed in the market should it induce any post market activities and hence it should not attract any annual charge for that period. In addition, once a product is launched to market, it requires an equal amount of post market activities regardless of its turnover for the year. Therefore, except for small businesses, we propose that eligibility for LVT exemption should be limited to those Register entries of zero turnover only. This change is similar to Option 3, but with the proposal to broaden the with definition of "no supply" to the Australian market to include:

- Register entries for export purpose. Some export markets do not accept CPP (Certificate of Pharmaceutical Product) of Export-only listed medicines, as such, the product needs to be listed as for the Australian market but are not marketed domestically.
- Register entries which are listed for the Australian market, but not launched into the Australian market until the next financial year due to many factors (strategy planning, production issues, logistics problems, etc.)

The eligibility restriction to zero-turnover Register entries for non-small businesses may also help to rectify the high ratio LVT exemptions from large sponsors. In 2012-13, the top 20 sponsors had an average of 611 entries/ sponsor with 1 in every 2 entries eligible for LVT exemption; whilst the remaining 3,530 sponsors had an average of 17 entries/ sponsor with 1 LVT exemption in every 4-5 entries.

With the implementation of this change, we also expect potential reductions in annual charges as discussed in option 3 of the consultation paper.

Percentage reduction in annual fees required for to be paying no additional annual charge, if the above changes are implemented is: