Submission No. 33

Review of the low value turnover exemption scheme

A response to the TGA Consultation paper, 10 April 2014

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2 Executive Summary

Medtronic Australasia understands there are issues with the current LVT exemption scheme one of which is that the current use of the LVT scheme is not consistent with the original policy statement, specifically that the three biggest beneficiaries of the scheme are generic medicines manufacturers.

Medtronic currently uses the LVT exemption scheme to claim exemption for ARTG entries which meet the current defined criteria of 15 times the annual fee.

These ARTG entries and the medical devices associated with them are kept on the Australian market, in part because Medtronic is able to claim these exemptions, and removal of the exemption would require Medtronic to review all those ARTG's to identify which devices are uneconomical to remain on the market.

The drawback is the complexity of the scheme which has meant the annual LVT exemption process does consume resources each year and we do carry out cost/benefit analysis whether to do a LVT application each year, but overall the burden is negligible.

Medtronic supports the continuation of the scheme in its current form, but acknowledges that some amendments to improve its efficiency would be beneficial especially for small companies, as long as Australia's commitments to the Free Trade Agreement are met.

3 Medtronic Profile

As an active participant in the Australian medical device environment for more than 40 years, and internationally for over 60 years, Medtronic has witnessed considerable change in the evaluation processes for new medical technology.

Medtronic is well-positioned to comment on the impact of existing processes and provide recommendations to improve process efficiency, reduce duplication and unnecessary complexity, as well as decrease regulatory costs that can combine to impede medical innovation in Australia.

Company Description
Medtronic is the global leader in medical technology- alleviating pain, restoring health and extending life for people with chronic conditions around the world. Medtronic develops and manufactures a wide range of products and therapies with emphasis on providing a complete continuum of care to diagnose, prevent and monitor chronic conditions. Each year, Medtronic therapies help more than seven million people.

Founded
April 29, 1949 in Minneapolis, Minnesota, USA, by Earl E. Bakken and Palmer J. Hermundslie.

Global Presence
Medtronic conducts business in more than 120 countries, with the World Headquarters based in Minneapolis, Minnesota USA. Medtronic Australasia is headquartered in Sydney.

Workforce
Medtronic employs more than 45,000 people worldwide and more than 450 in Australia.

4 What is the problem to be addressed?

Research traces the establishment of the LVT scheme to a policy objective of supporting manufacturers of small volume products, small start-up companies, herb growers and small companies making medical appliances whose turnover on a number of product lines might only be a few hundred or a few thousand dollars.

The current consultation paper indicates that the LVT scheme does not seem to address these original objectives especially as the three biggest beneficiaries of the scheme are generic medicines manufacturers, who may not fit into the original policy objective.

Another issue would be the fact the TGA is a fully cost recovered regulator and the establishment of the LVT scheme in 1990 was before the implementation of the cost recovery model in 1999, resulting in a form of cross subsidy which may be inconsistent with the Australian Government Cost Recovery Guidelines.

5 Objectives of the Consultation

To identify issues and the financial impact that might be faced by sponsors and stakeholder groups as a result of each of the options;

Feedback on whether the removal, or changes to, the LVT scheme would limit your ability to enter or maintain goods on the Register;

Feedback on whether the implementation of any of the options presented could lead to cessation of supply of essential therapeutic goods, causing potential public health risks;

Feedback on other options which may achieve the objectives but that may not have been considered; and

To use the feedback received to arrive at the outcome of the review and to help devise appropriate mechanisms to implement changes, if any required

6 Addressing the Options

6.1 Option 1 – Retain the LVT scheme in its current form

Concerns around the current LVT scheme, outlined in the consultation paper, include ineffectiveness in meeting its policy objectives, inequity, administrative burden and inconsistency with the guideline thus it is not desirable to continue the scheme in its current form.

Implications

Medtronic does make use of the LVT exception scheme to ensure we do not pay fees on ARTG entries which meet the requirement of not receiving revenue less than or equal to 15 times the annual fee.

This does mean that products which have very little or no sales can remain on the ARTG if required without decisions needing to be taken on whether to remove access of the product from the Australian market.

Medical devices companies can and do keep access to older products, which may have limited sales or with current niche or specific indication products. The options to supply some of these devices say via the SAS process add administrative difficulties and planning restraints for HCP's, additional costs for the TGA to administer the additional SAS applications and logistical issues with bringing unapproved product into Australia for specific cases.

The broader benefit is that Medtronic is able to offer a wider range of products and keep low utilization medical devices on the market.

The drawback is the complexity of the scheme which means the annual LVT exemption process does consume resources each year and we do carry out cost/benefit analysis whether to do a LVT application each year, but overall the burden is negligible.

Recommendations

The current system works, in the medical device area, where the original objective of ensuring small volume products are kept on the Australian market is being met.

6.2 Option 2 – Retain the LVT scheme, with some amendments to improve its efficiency.

The consultation paper discusses that, one of the primary objectives of the introduction of the LVT scheme was to provide relief to small businesses upon the introduction of therapeutic goods regulation and thus this option has been proposed.

Care should be taken to only pull out one of the original primary objectives of the LVT scheme, that of providing relief to small business whereas supporting manufacturers of small volume products is very important especially with regards to medical devices where a product could be for a niche indication or patient population.

Whilst it is noted that there are challenges with the current LVT scheme in achieving that intended objective, given the widespread use of the scheme, one option would be to continue the scheme, with some amendments to improve its administration and efficiency.

Implications

We have already stated Medtronic supports the continuation of the LVT scheme in its current form without any changes (option 1) but have looked at this option to understand the implications to Medtronic on the improvements to the LVT administration and efficiency as described in the consultation paper.

Medtronic is unsure how clarification of “turnover” will help make the scheme better, one point made in the consultation paper is that three quarters of LVT benefit is received by prescription medicines therefore maybe rather than a blanket “turnover” there could be review of this by therapeutic area.

Removal of deadlines would not improve the scheme as it is down to individual planning to meet the deadline and unless the rules on paying of fees by 1st October are changed to allow for a late application to be processed any late application will require the fee to be paid, then a refund or credit to be issued at a later date all of which will add to the work load of the TGA.

The self-declaration for smaller businesses may be fairer as the cost of having an accountant come into our business is significant and the administrative burden required certifying an application for a few ARTG’s is not that much greater than for several ARTG’s. This would need to be assessed against the requirements of the Free Trade Agreement commitments, as may be constituted as a technical barrier to trade.

Removal of the cap on the application fee may align more with cost recovery guidelines and may make the process fairer as larger companies applying for exception for over 100 ARTG’s would pay more to have these products exempt, but Medtronic feels that the TGA needs to understand the real costs of administering the scheme as there is administrative efficiencies with the increasing number of ARTG’s within an application so a blanket removal of the cap would not be acceptable and would not align with cost recovery guidelines.

This would then also mean the LVT exception would not apply to class I medical devices as the fee for exception would be greater than the annual fee.

Recommendations

Medtronic supports the continuation of the scheme in its current form (option 1),

but acknowledges that some amendments to improve its efficiency would be beneficial especially for small companies.

Removal of the cap should only be done with clear understanding of the real costs of administering the scheme as there are administrative efficiencies with the increasing number of ARTG's and charges need to align with cost recovery guidelines

6.3 Option 3 – Replace the LVT scheme with one that only grants exemptions for Register entries which are not supplied to the Australian market

Another option under consideration is restriction of the LVT scheme to only those Register entries which are not supplied to the Australian market.

The rationale for this option is that, as these products are not marketed in Australia they require minimal post-market surveillance and monitoring by the TGA. Given the low post market cost of these Register entries, another option could be to establish a lower charge for these entries and remove the LVT scheme.

Under this option, all Register entries reporting annual turnover in excess of zero (largely those products which are actively marketed in Australia, and which therefore are subject to post market monitoring and compliance), would contribute to the costs of post-market functions.

Implications

Maximum fee reduction of 10% is indicated (as long as no ARTG's are cancelled). Interestingly the indicated fee reduction in this case is only 10% compared to scrapping the LVT scheme completely which indicates 22% fee reduction for medical devices (in the best case with no entries being cancelled) thus there still seems to be some form of cross subsidy being applied with this option.

Medtronic would require clarity on whether this option relates to marketing or supply of a product. Medtronic has ARTG entries which would qualify in that they have $0 turnover. This option is unclear and contradictory in that it first talks about supply and the need for post market on supplied product but then the measure is $0 turnover for the product to qualify. We would assume this option would allow product not supplied within one fiscal year to be exempt but if one was sold the next financial year then the full fee would be applied.

The financial planning within this option would be onerous to our business and Medtronic would have a significant net loss financially. An ARTG entry of small volume products is very important. This is especially true with regards to medical devices where a product could be for a niche indication or patient population, thus these products may no long be available on the Australian market

Recommendation

Medtronic does not support this option. It is unclear whether implementing this option would have the desired impact and $0 turnover does not support the policy objective of supporting manufacturers of small volume product and could potentially remove medical devices which have a niche indication or patient population from the Australian market.

6.4 Option 4 – Replace the LVT scheme with one that only grants exemptions for Register entries where the sponsor is a small business

Implications

Medtronic would lose all rights to a LVT exemption but this would be offset by a proposed maximum reduction in fees of around 22% (for medical devices if no entries being cancelled).

Medtronic would have a significant net loss financially and as discussed previously ARTG entries of small volume products are very important. This is especially true with regards to medical devices where a product could be for a niche indication or patient population, thus these products may no long be available on the Australian market.

It is difficult to say exactly how many products would be taken off the market as they would all need to be assessed on an individual basis.

Medtronic would also question whether this option would be seen as breaching competition practices and would need to be assessed against the requirements of the Free Trade Agreement commitments, as may be constituted as a technical barrier to trade.

Recommendations

Medtronic does not support this option, as it does not support the policy objective of supporting manufacturers of small volume product and could potentially remove medical devices which have a niche indication or patient population from the Australian market.

6.5 Option 5 – Cease the LVT scheme completely

This option would involve the cessation of the LVT scheme at the commencement of the 2015-16 financial years, subject to Regulation changes.

It has been indicated that it is expected that a high portion of sponsors would benefit from ‘across the board’ decreases in annual charge rates for individual Register entries, this is partially obvious if you are a prescription medicines sponsor with a 62% reduction in fees, but significantly smaller reductions would apply for Medical Device sponsors.

Implications

Medtronic would lose all LVT exemptions but this would be offset by a proposed maximum reduction in fees of around 22% (for medical devices if no entries were being cancelled).

Medtronic would have a significant net loss financially and as discussed previously ARTG entries of small volume products are very important. This is especially true with regards to medical devices where a product could be for a niche indication or patient population, thus these products may no long be available on the Australian market.

It is difficult to say exactly how many products would be taken off the market as they would all need to be assessed on an individual basis, also there will be additional costs for the TGA to administer the additional SAS applications.

Recommendation

Medtronic does not support this option, as it does not support the policy objective of supporting manufacturers of small volume product as this option could potentially remove medical devices which are niche indication or patient population from the Australian market.

7 Summary

Medtronic welcomes this opportunity to provide input into the discussion regarding review of the LVT Scheme.

Medtronic does not support the cessation of the scheme, restricting the scheme to small companies or restricting the exemptions to items not supplied to the Australian market or $0 turnover, as this may result in small volume products being removed from the market.

There will also be additional costs for the TGA to administer the additional SAS applications.

Medtronic supports the continuation of the current scheme in its current form but does see some value from some of the amendments put forward to ensure fairness for small companies as well as ensuring there is no cross subsidy in the LVT application process but administrative efficiencies need to be realized to align with cost recovery guidelines.

All options will need to be assessed against the requirements of the Free Trade Agreement commitments, as may be constituted as a technical barrier to trade.