Submission No. 19

CHC Submission to the Therapeutic Goods Administration
Review of the Low Value Turnover Exemption Scheme

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The Complementary Healthcare Council of Australia (CHC) welcomes the opportunity to provide its response to the Therapeutic Goods Administration (TGA) on a policy and operational review of the low value turnover exemption scheme (LVT) as outlined in the discussion paper dated, 10 April 2014.

The CHC represents all stakeholder groups in the complementary healthcare industry. Our members include importers, exporters, manufacturers, raw material suppliers, wholesalers, distributors, retailers, practitioners, consultants, direct marketers, multi level marketers and consumers.

The consultation paper outlines the basis for the review of the LVT scheme and includes the following factors:

- A 2009 ANAO recommendation that tighter controls be applied to verifying product eligibility for the scheme. This has occurred through the TGA requiring independent certification of product turnover values.
- The number of complaints received from industry in relation to:
    - unnecessary administrative burden
    - inflexible timing for annual LVT applications
    - level and determination of key financial parameters
    - magnitude of difference in outcome between products that are marginally eligible, compared to those that are marginally ineligible

In general, whilst acknowledging that complaints are received in relation to the administrative matters detailed above, these factors alone should not give rise to a situation where the LVT scheme itself is abolished.

The consultation paper provides for the background of the policy objectives to the LVT scheme in that it was originally established to support manufacturers of small volume products, small start up companies, herb growers and the like.[1] More recent analysis of the figures does indicate that the top 20 sponsors received more than 50% of the LVT exemptions, the three largest beneficiaries being related to the manufacture of generic medicines. Even presented with this summation, it does not necessarily mean that the LVT policy is no longer delivering on its main objectives; rather it may simply be that the scheme is being utilised by a wider than originally intended audience. This scenario should form the basis for further discussion on policy reform.

Whilst the statement that the removal of the LVT scheme could generate savings on annual charges across the therapeutic goods sector by up to 62% is significant, it may be that the potential savings gained by SMEs'[2] use of the LVT scheme would be more valuable to that

[1] Senate Official Hansard No.142, 1990, Commonwealth of Australia, accessed 16 May 2014, Page 141 <http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;db=CHAMBER;id=chamber%2Fhansards%2F1990-12-20%2F0218;query=Id%3A%22chamber%2Fhansards%2F1990-12-20%2F0000%22>

[2] Note: The Australian Taxation Office defines small-to-medium enterprises as economic groups with turnover of $2 million to $250 million.

business year over year than the percentage change to annual fees as consulted with the complementary medicine sector each year.

The CHC provides the following comment on the options outlined in the consultation paper:

1. Retain the LVT scheme in its current form
2. Retain the LVT scheme, with some amendments to improve its efficacy
3. Replace the LVT scheme with one that only grants exemptions for Register entries which are not supplied to the Australian market
4. Replace the LVT scheme with one the only grants exemptions for Register entries where the sponsor is a small business
5. Cease the LVT scheme completely

The CHC is supportive of option 2 to retain the LVT scheme with amendments to assist small to medium sized business with a better targeted and lower-burden scheme.

The CHC in general is supportive of a policy that provides SMEs, the original intended beneficiaries of such a policy, to continue to utilise the LVT scheme, with the suggestion to further reduce the administrative burden on the certification of the scheme by accepting self declarations and/or conducting a desk top audit review of the process on a risk basis. This would also likely address some of the reported reasons why small business uptake of the scheme may be lower than ideal (page 15).

The CHC queries, regarding the implementation of the ANAO recommendation, the interpretation of 'tighter controls' for the scheme. Could this have been interpreted in another manner rather than to impose the services of an independent certifier to verify eligibility for the scheme each and every financial year (and other validation requirements)?

The CHC proposes that rather than impose the services of an independent certifier to verify eligibility for the scheme every financial year, a level of certainty could be achieved from the use of other changes to the LVT scheme. For example, applicants could be subject to an audit type situation where the applicant would only be required to submit certified documents for a specific financial year in either a random or targeted manner, and possibly based on an overall risk profile. This would achieve a decrease in administrative burden and increased flexibility of the system whilst still subjecting users to independent auditing.

Further changes to assist small business to utilise the LVT Scheme - such as clarifying the definition of 'turnover', providing provisions for the extension of deadlines within the Regulations (possibly with a late lodgement fee) and accepting self-declarations of turnover from small business are all valid places to continue the policy reform discussion.

In a most basic approach, the LVT scheme should be maintained as an option for products entered late in the last quarter of the financial year (April, May, June), which logistically are unlikely to have been supplied to customers and hence may not have achieved sales. Alternatively the first annual charge could be on a pro rata basis or revert to either quarterly or 6 monthly invoicing in the first year.

The CHC provides comment on the following essential questions

1. Is there a contemporary policy need for an LVT scheme?

   The CHC is supportive of option 2 to retain the LVT scheme with amendments. The CHC agree that a review of the LVT scheme is required. The review should seek to reduce administrative burden where possible while allowing for the continuation of an avenue for bringing new or novel medicines to Australian consumers.

2. Are there any other policy options available to address the policy need?

   The CHC has outlined some conceptual options for TGA consideration which we would welcome further exploration.

3. Is there a problem with the operation of the current LVT scheme?

   The CHC supports maintaining a scheme that achieves its original intent of assisting manufacturers of small volume products and SMEs. We do not believe that enough evidence of a problem has been presented to justify termination of the scheme entirely, although we acknowledge the potential cost recovery benefits that may be gained by the prescription therapeutic products sector[3].

4. What are the policy options and what is the net benefit of each of those options?

   The CHC has provided preliminary suggestions for alternate policy options for further consideration.

5. How compatible is each option with other Government policy such as the Australian Government Cost Recovery Guidelines and Competition Policy?

As detailed earlier, the suggestion of moving to an auditing type approach for compliance with applicants' appropriate use of the scheme on a risk basis, is compatible with the sentiment of the Charges Regulations, in that varied levels of charges are prescribed for different classes of therapeutic goods - such as complementary medicines, based on the level of risk associated with that type of good.

We therefore consider the proposals outlined in this paper to be compatible generally with the objectives of the Department of Finance and Deregulation whole-of-Government review of cost recovery guidelines.

We suggest that policy proposals seeking to reduce excessive regulatory burden, or minimise the identified administrative burden, speaks to the Governments' $1 billion annual regulation cost reduction target.[4]

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[3] Review of the low value turnover exemption scheme, Therapeutic Goods Administration, accessed 16 May 2014, Table 4, page 18 <http://www.tga.gov.au/pdf/consult/consult-ocs-lvt-exemption-140410.pdf?>

4 Office of Deregulation, Department of Prime Ministers and Cabinet, accessed 19 May 2014, <http://www.dpmc.gov.au/deregulation/>