Submission No. 7

AusBiotech response to the review of the low value turnover exemption scheme

To: The Therapeutic Goods Administration
Australian Government
Email: lvtconsultation@tga.gov.au

23 May 2014

From: AusBiotech Ltd
ABN 87 006 509 726
Level 4, 627 Chapel St
South Yarra VIC 3141
Telephone: +61 3 9828 1400
Website: www.ausbiotech.org

Submission No. 7

Introduction

AusBiotech is a well-connected network of over 3,000 members in the life sciences, including bio-therapeutics, medical technology (devices and diagnostics), food technology and agricultural biotechnology sectors. AusBiotech supports the biotechnology industry, which is characterised by small and start-up companies developing new technologies.

AusBiotech welcomes the opportunity to comment on the various options outlined in the TGA's consultation paper: *Review of the low value turnover exemption scheme*. Note that this represents a specific response from AusMedtech, part of AusBiotech representing the medical technology industry, and therefore the proposed options have been reviewed in the context of AusBiotech's medical device (including in vitro diagnostic devices) member companies' experience with the low value turnover (LVT) scheme.

Low value turnover exemption scheme (LVT)

AusMedtech's perspective is that it is the membership's large, well established companies that have been the most significant users of the LVT scheme with only a very low number of small businesses taking advantage of the scheme despite their products being eligible. This certainly reflects the general experiences expressed, and data presented, in the consultation paper by the TGA. The main reasons cited for AusMedtech's small businesses not using the scheme are:

1. The administrative burden of applying for the exemption under this scheme outweighs the benefits;
2. There is a lack of awareness that the scheme exists; and
3. Even when made aware of the scheme, whilst this is seen as a valuable initiative, they have not actually been eligible due to the threshold being below their first year's anticipated revenue. Their opinion is that the threshold has been set too low to compensate for the investment that has, to that stage, been made in the business. If it were higher this would assist greatly in getting them through the critical first year of business and the exemption would likely only be needed for that first year.

AusMedtech believes that, whilst the use of the current scheme has drifted from the original policy intent there does remain a contemporary policy need for an LVT scheme. Therefore AusMedtech does not support Option 5, which is to cease the scheme completely. An alteration to the scheme is required to re-align the actual use of the scheme with desired policy aims. AusMedtech proposes that the objectives of the amended scheme should be primarily to:

1. Support the provision of therapeutic goods that might otherwise not be viable in the market: and
2. Support equivalent access to the program for small companies

Ideally both of these objectives can be achieved within the framework of a least-burdensome approach to administering such a scheme.

Specific comments in response to each option proposed shall be provided, however, AusMedtech would initially like to provide some general comments in response to the detailed and useful information and data provided by the TGA in this consultation paper.

General Comments

The scheme appears to be a well-used scheme if 47% of the total invoiced annual charges fell under the LVT exemption and therefore were not collected for the year 2012-13. It also appears that the bulk of the sponsors using the scheme represent larger companies, from a product portfolio perspective. This is also reflected in the feedback received from AusMedtech companies in response to this consultation paper. Larger companies are more heavily represented in the use of the LVT scheme compared with small businesses. AusMedtech agrees that the objectives of the LVT scheme developed when it was conceived are not reflected in the way in which the current scheme is being used and that an alteration to the scheme to bring it into alignment with the proposed contemporary objectives stated above would be beneficial.

AusMedtech shares the TGA's concern that elimination of the scheme or significant alteration of the scheme to allow exemption based on company turnover rather than on individual Register entry turnover would result in a reduction in the number and types of products available to the Australian public due to sponsor's cancelling entries no longer eligible for annual fee exemption. This would be the unintended consequences of restricting the LVT scheme to small businesses in an effort to address the current very low number of small businesses taking advantage of the scheme. AusMedtech notes that the TGA states that there is an alternative scheme [Special Access Scheme (SAS)] to support the provision of essential therapeutic goods that might otherwise not be viable in the market. Whilst this is an alternative scheme that could be used, AusMedtech does not believe this to be a viable alternative. It is preferable for Australians to have access to approved products. Timely access to products also may be compromised and promotion of products under the SAS is not allowed. The administrative burden for clinicians, suppliers and the TGA would also be adversely impacted.

The heavily favoured option is option 2, continuing with the LVT scheme in its current form, but amended as indicated in the specific response to option 2 (below). AusMedtech wishes to see small businesses encouraged and supported. Whilst the scheme appears not to be used as much by small business currently, a diligent investigation of the root cause(s) for this should be conducted and these root causes addressed, rather than seeking to remove the availability of the scheme from the current beneficiaries. Denying access to the larger companies that currently benefit from the scheme would likely result in cancellation of some current entries and potentially limit the introduction of new LVT products. This would be to the detriment of the Australian public that is serviced by the availability of these products. AusMedtech recognises that this consultation paper is a very good start in identifying what the root causes may be. There is value in reaching out to small business owners as a specific sub-group of potential users to identify why they are not using the scheme and to validate assumptions expressed in this consultation paper.

Specific comments for each option follow.

Option 1: Retain the LVT scheme in its current form

1. **Do you support the option of continuing with the LVT scheme in its current form?**

   AusBiotech does not support the option of continuing with the LVT scheme in its current form, however retaining the LVT scheme in its current form is preferable to abolishing the scheme.

   The current scheme seems to no longer be addressing the aims of the initial policy that led to its implementation. The benefits also are outweighed by the burden of the current application and validation process, in particular for smaller businesses.

2. **Is your business a beneficiary of the current LVT scheme? If you are currently claiming any LVT exemptions, how do the exemptions provide a benefit to your business?**

   A number of AusMedtech member companies benefit from the current LVT scheme. The continued supply of low volume niche products is supported by the LVT scheme.

3. **If you're not currently claiming any LVT exemptions, please explain the reasons for this, particularly if you have entries which could qualify as low value turnover entries.**

   Smaller businesses report that the administrative burden associated with the process outweighs the benefits. There has also been one report of the threshold being too low to compensate for the investment that has, to that stage, been made in the business. If it were higher this would assist greatly in getting through the critical first year of business and the exemption would likely only be needed for the first year.

4. **What do you see as the broader benefits of the current LVT scheme?**

   The Australian public has access to a greater selection of therapeutic goods than if a LVT scheme did not exist.

   The resultant greater selection provides more competition in the market.

5. **What do you see as the drawbacks of the current LVT scheme?**

   The current LVT scheme is not addressing the aims of the initial policy that led to its implementation. The benefits also are outweighed by the burden of the current process, in particular for smaller businesses.

Option 2: Retain the LVT scheme with some amendments

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.**

   AusMedtech supports this option and agrees that the LVT scheme should be retained with amendments that would bring it into alignment with the desired objectives of:

   a. Supporting and encouraging equivalent access to the scheme for small business in Australia; and

   b. Supporting the provision of therapeutic goods that might otherwise not be viable in the market.

   In response to specific amendments suggested in the consultation paper:

   - The current definition of turnover may require redefinition in light of some comments by a smaller business that a higher threshold would assist in the first year of market entry, although on balance most member companies responding to this consultation find the current turnover threshold (15 times the annual charge) to be appropriate for medical devices. It is noted that 75% of the LVT benefit returned is received for prescription medicines and only 11% for medical devices. It may be appropriate to adapt the definition of turnover for each therapeutic category.
   - AusMedtech has no objections to the TGA providing provision in the Regulations for an extension of deadline for submitting an LVT application or removing the option for submitting validation information for new entries in the prior year so that the deadlines for the two processes cannot be confused. AusMedtech would however prefer that the TGA accept self-certification instead, to completely simplify the process and reduce the costs to sponsors and the TGA of administrating an onerous application process.
   - AusMedtech has no objection to self-declaration from small businesses, however, does recommend self-declaration across all businesses, irrespective of size.
   - AusBiotech does not support the removal of the $15,000 annual cap and this would be made redundant in any case if the recommendations of the much less burdensome self-declaration process are followed. The resultant lower costs of managing a much less burdensome LVT scheme would result in savings that could be applied to reducing annual fees.

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

   This option is in keeping with both of the key original and contemporary policy objectives of supporting and encouraging success of small business in Australia and, supporting the provision of therapeutic goods that might otherwise not be viable in the market.

   It is anticipated that the costs of managing a much less burdensome LVT scheme would result in reduced annual fees.

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

Removing the annual cap of $15,000 will increase the fees for sponsors with a high number of low volume products.

There would be no drawbacks if the proposed annual cap amendment is not a part of the alterations ultimately approved.

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

Focussing on the root causes of the very low numbers of smaller businesses using the LVT scheme is suggested by:

a. Addressing the high burden of administration involved with the current scheme, for both the TGA and for sponsors. AusMedtech proposes that a process of self-declaration (with spot auditing) would be sufficient and would eliminate the current application processing burden on both the sponsor and TGA. It is envisaged that this would also eliminate or heavily reduce the $150 LVT assessment fee per entry, recovered under the current system. The efficiencies gained in not having to maintain the current system of assessing every LVT but rather maintaining a lower cost process of spot auditing and penalising those companies that choose to abuse the LVT self-declaration would have the flow-on effect of reducing annual fees.

b. Addressing the lower awareness of small businesses of the availability of the LVT scheme. For example, an awareness note to sponsors could be triggered from the TGA/eBS system when they apply for Client ID and/or eBS access to indicate the existence of the LVT scheme. This would ensure all sponsors, including the smaller businesses that are less likely to be aware of the existence of the scheme would become aware of this option.

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

1. **Do you support the option of confining eligibility of annual charge exemptions to only those Register entries which are not supplied in Australia or establish a lower annual charge for such entries? Please mention which option (LVT for zero turnover products or lower annual charge) you prefer and detail why you hold this view and any variations to this option that could improve its operation.**

   AusBiotech does not support this option.

   There are likely to be a very low number of entries for which this would apply. The greatest number would fall within the 'export only' category and these are exempt of annual charges already. The limited benefits achieved by moving to this option are far outweighed by the negative impact on AusMedtech member companies that currently receive LVT exemptions.

2. **How would this change impact your business? Would these changes be largely positive or negative, taking into account the expected benefits and disadvantages? Please include financial impacts, changes to marketing of products etc.**

   On balance the impact on member companies' businesses would be negative. Whilst it is acknowledged that annual fees may be reduced as a consequence of moving to this option, the benefits gained in that regard are not commensurate with losses incurred by ceasing the exemptions. For member companies this would result in a review of the economic benefits of supplying certain products and potentially their removal from the Register.

3. **If this change was implemented, would this impact on your supply of products into the Australian market? If yes, please provide more detail on these expected impacts.**

   Yes, as indicated in #2 above. A detailed analysis would need to be undertaken to determine exactly which products would be removed from the Register as a consequence of this option playing out, however feedback from those member companies that chose to provide comment on this consultation paper to AusMedtech all indicated that products would certainly be removed.

   AusMedtech notes that the TGA states that there is an alternative scheme [Special Access Scheme (SAS)] to support the provision of essential therapeutic goods that might otherwise not be viable in the market. Whilst this is an alternative scheme that could be used, AusMedtech does not believe this to be a viable alternative. It is preferable for Australians to have access to approved products. Timely access to products also may be compromised and promotion of products under this scheme is not allowed. The administrative burden for clinicians, suppliers and the TGA would also be adversely impacted.

4. **What do you see as the broader benefits of this option?**
Whilst this option is designed to address the concerns regarding cross-subsidisation that is an outcome of the current scheme, the perceived benefits of reduced annual fees as a result of the elimination of cross-subsidization would not balance the loss of exemptions. Also, it is expected that the LVT products represent less post market activity costs to the TGA by the very nature of them being at lower volumes and therefore the actual cross-subsidisation is not as pronounced as depicted.

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

Under this option a company would still need to account for each product separately and demonstrate zero turnover through an application process and there is potential for this to still be somewhat burdensome. AusMedtech's proposed self-declaration process is preferred.

Whilst applying this option could result in a reduction in annual charges, it is generally felt by AusMedtech companies currently using the LVT scheme that the benefits of reduced annual fees would not balance the loss of the exemptions and therefore a proportion of entries would be cancelled as a result. This option therefore does not address the specific objective of supporting the provision of therapeutic goods that might otherwise not be viable in the market. It is noted that 374 out of 974 sponsors would be affected by this change. AusMedtech shares TGA's concern that these sponsors may decide to cancel products from the Register reducing availability and choice for the Australian public.

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

1. **Do you support the option of confining eligibility of annual charge exemptions to small business?**

   AusMedtech does not support this option.

   The exemption is based on business turnover rather than the turnover of individual entries. This addresses the proposed objective of assisting small businesses, however, will likely have the unintended consequence of limiting the supply of devices on the Australian market.

2. **How would this change impact your business? Would these changes be largely positive or negative, taking into account the expected benefits and disadvantages? Please include financial impacts, changes to marketing of products etc.**

   On balance the impact on member companies' businesses would be negative. Whilst it is acknowledged that annual fees may be reduced as a consequence of this change to the scheme, the benefits gained in that regard are not commensurate with losses incurred by ceasing the exemptions. For member companies impacted this would result in a review of the economic benefits of supplying certain products and potentially their removal from the Register.

3. **If this change was implemented, would this impact on your supply of products into the Australian market? If yes, please provide more detail on these expected impacts.**

   Yes, as indicated in #2 above. A detailed analysis would need to be undertaken to determine exactly which products would be removed from the Register as a consequence of this option playing out, however feedback from those member companies that chose to provide comment on this consultation paper to AusMedtech all indicated that products would certainly be removed.

   AusMedtech notes that the TGA states that there is an alternative scheme [Special Access Scheme (SAS)] to support the provision of essential therapeutic goods that might otherwise not be viable in the market. Whilst this is an alternative scheme that could be used, AusMedtech does not believe this to be a viable alternative. It is preferable for Australians to have access to approved products. Timely access to products also may be compromised and promotion of products under this scheme is not allowed. The administrative burden for clinicians, suppliers and the TGA would also be adversely impacted.

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

   Applying the ATO definition and the proposed way in which information is collected greatly simplifies the process for both TGA and sponsor, however, AusBiotech's proposed self-declaration process would reduce burden even further.

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

Whilst applying this option could result in a reduction in annual charges, it is generally felt by AusBiotech companies currently using the LVT scheme that the benefits of reduced annual fees would not balance the loss of the exemptions and therefore a proportion of entries would be cancelled as a result. This option therefore does not address the specific objective of supporting the provision of therapeutic goods that might otherwise not be viable in the market.

This option may also not meet commitments required by The Free Trade Act.

Option 5: Cease the scheme completely

1. **Do you support the cessation of the LVT scheme? Please detail why you hold this view.**

   AusMedtech does not support the cessation of the LVT scheme.

   AusMedtech believes that, whilst the use of the current scheme has drifted from the original policy intent there does remain a contemporary policy need for an LVT scheme. A need remains for a scheme to support and encourage access by all businesses in Australia and, to support the provision of therapeutic goods that might otherwise not be viable in the market. Cessation of the scheme without replacing it with an alternative scheme to satisfy these key objectives is not in the interests of stakeholders.

2. **How would this change impact your business? Would this change be largely positive or negative, taking into account the expected benefits and disadvantages? Please include financial impacts, changes to marketing of products etc.**

   On balance the impact on member companies' businesses would be negative. Whilst it is acknowledged that annual fees may be reduced as a consequence of cessation of the scheme, the benefits gained in that regard are not commensurate with losses incurred by ceasing the exemptions. For member companies impacted this would result in a review of the economic benefits of supplying certain products and potentially their removal from the Register.

3. **If this change was implemented, would this impact on your supply of products into the Australian market? If yes, please provide more detail on these expected impacts.**

   Yes, as indicated in #2 above. A detailed analysis would need to be undertaken to determine exactly which products would be removed from the Register as a consequence of this option playing out, however feedback from those member companies that chose to provide comment on this consultation paper to AusMedtech, all indicated that products would certainly be removed.

   AusBiotech notes that the TGA states that there is an alternative scheme [Special Access Scheme (SAS)] to support the provision of essential therapeutic goods that might otherwise not be viable in the market. Whilst this is an alternative scheme that could be used, AusMedtech does not believe this to be a viable alternative. It is preferable for Australians to have access to approved products. Timely access to products also may be compromised and promotion of products under this scheme is not allowed. The administrative burden for clinicians, suppliers and the TGA would also be adversely impacted.

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

   Perceived benefits of reduced annual fees as a result of the elimination of cross-subsidisation would not balance the loss of exemptions. Also, it is expected that the LVT products represent less post market activity costs to the TGA by the very nature of them being at lower volumes and therefore the actual cross-subsidisation is not as pronounced as depicted.

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

Submission No. 7

This option is not in-keeping with original and contemporary policy objectives of assisting small businesses and supporting the provision of therapeutic goods that might otherwise not be viable in the market.