Comments on the Review of the Low Value Turnover Exemption Scheme

May 2014

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Our Credo

We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality. We must constantly strive to reduce our costs in order to maintain reasonable prices. Customers' orders must be serviced promptly and accurately. Our suppliers and distributors must have an opportunity to make a fair profit.

We are responsible to our employees, the men and women who work with us throughout the world. Everyone must be considered as an individual. We must respect their dignity and recognise their merit. They must have a sense of security in their jobs. Compensation must be fair and adequate, and working conditions clean, orderly and safe. We must be mindful of ways to help our employees fulfil their family responsibilities. Employees must feel free to make suggestions and complaints. There must be equal opportunity for employment, development and advancement for those qualified. We must provide competent management, and their actions must be just and ethical.

We are responsible to the communities in which we live and work and to the world community as well. We must be good citizens - support good works and charities and bear our fair share of taxes. We must encourage civic improvements and better health and education. We must maintain in good order the property we are privileged to use, protecting the environment and natural resources.

Our final responsibility is to our stockholders. Business must make a sound profit. We must experiment with new ideas. Research must be carried on, innovative programs developed and mistakes paid for. New equipment must be purchased, new facilities provided and new products launched. Reserves must be created to provide for adverse times. When we operate according to these principles, the stockholders should realize a fair return.

Background

Johnson & Johnson is the world's most comprehensive and broadly-based manufacturer of healthcare products. Our success and reputation over the years has been achieved through the commitment, efforts and values of all the people who have made Johnson & Johnson the company it is today. It is also why we are consistently recognised as one of the world's most admired companies within the healthcare sector and by the communities in which we operate/people who use our products.

Through our consumer, medical device and pharmaceutical companies we have the unique privilege of touching the lives of over one billion people every day throughout the world. Our consumer products range from skincare, to over-the counter medicines, to smoking cessation aids and a portfolio of leading brands, which includes JOHNSON'S® Baby, CODRAL®, BAND-AID® Brand Adhesive Bandages, LISTERINE® Antiseptic Mouthwash, and ACUVUE® Brand contact lenses. Johnson & Johnson Medical is a leading provider of medical devices used primarily by health care professionals in the fields of orthopaedics, neurovascular, surgery, diabetes care, infection prevention and aesthetics. Janssen Pharmaceutical Companies are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g. multiple myeloma and prostate cancer), immunology (e.g. psoriasis), neuroscience (e.g. schizophrenia, dementia and pain), infectious disease (e.g. HIV/AIDS, Hepatitis C and tuberculosis), and cardiovascular and metabolic diseases (e.g. diabetes). Tasmanian Alkaloids produces raw materials for over 20% of the world's legal pain control products and our Ortho Clinical Diagnostics business serves the transfusion medicine community and laboratories around the world.

Caring for the world, one person at a time... inspires and unites the people of Johnson & Johnson. We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people.

Introduction

The Johnson & Johnson Family of Companies (J&J) welcomes and appreciates this opportunity to comment on the Therapeutic Goods Administration's (TGA) review of the Low Value Turnover Exemption Scheme (the LVT scheme).

In response to the consultation, a submission that represents the J&J Family of Companies is being provided. For the purposes of this submission, the J&J Family of Companies includes Johnson and Johnson Medical Pty Ltd (EID 267); Johnson & Johnson Medical Pty Ltd T/A Depuy Australia (EID 10380); Janssen-Cilag (EID 268); Johnson and Johnson Pacific Pty Ltd (EID 786); OCD (30818) and Synthes (EID 969)

Across the Family of Companies, J&J supply a variety of therapeutic goods from each of the sectors regulated by the TGA and as such offer a unique industry position in this consultation process.

J&J acknowledges that the following are issues with the current LVT scheme and are therefore driving the proposed changes:

- Inequity through cross-subsidy of annual charges
- Administrative burden and costs associated with preparing and submitting a claim for an LVT exemption
- Inconsistency with the Government's Cost Recovery Guidelines

J&J agrees that a review of the current process is necessary but there is still a need for an exemption scheme which ensures patients continue to gain access to therapeutic goods which deliver positive health outcomes but may not be financially viable for a sponsor to supply.

J&J supports an appropriate cost recovery model for annual charges by the TGA. We recognise the importance of post-market regulatory activities and monitoring product safety and that annual charges must cover the associated costs. J&J also believes that such charges should continue to be based on the level of risk of the type of good.

J&J welcomes the potential for annual charges to fall by up to 62%[1] and is supportive of changes to the current LVT scheme which are balanced with a reduction in annual charges.

J&J are providing the following response with mostly general comments to begin the discussion around the proposed changes as further detail regarding TGA's calculation of annual charges is required. J&J therefore have a strong commitment to participating in future consultations.

It should also be noted that J&J has contributed to and/or broadly supports the submissions made by the following organisations:

- Medical Technology Association of Australia (MTAA)
- Australian Self Medication Industry (ASMI)

[1] TGA Consultation Paper: Review of the low value turnover exemption scheme, Version 1.0, April 2014

Option 1: Retain the LVT Scheme in its current form

Issues relating to Option 1

1. Do you support the option of continuing with the LVT scheme in its current form?
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?
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.
4. What do you see as the broader benefits of the current LVT scheme?
5. What do you see as the drawbacks of the current LVT scheme

1) J&J does NOT support the proposal to retain the current LVT scheme. Option 1 does not address the concerns raised by the TGA and which have been acknowledged as issues of the current scheme.

2) J&J, and ultimately the users of our products, benefit from the current scheme and received the following LVT exemptions in the 2013-2014 financial year:

3) Not applicable.

4) J&J sees that the broader benefits of the current scheme are:
   a. Financial benefit – exemptions are applied for products with nil quantities sold or products with a low turnover. The exemption for these products is typically commensurate with the level of post marketing activities required for these products.
   b. Enables supply of low volume/low sales of essential therapeutic goods. From a commercial perspective, there are a number of products that have limited financial benefit to a company (eg. specialised medicines or medical devices for small patient groups), and are supplied for ethical reasons. An exemption on these products is valuable as it helps reduce the overheads associated with the supply of these products.

5) J&J sees that the drawbacks of the current system are:
    a. Cross subsidisation (as described in the Consultation Paper) is not in keeping with the principle of true cost recovery.
    b. Administrative burden for both the TGA and sponsors, including the need for independent auditors to validate the exemption.
    c. Financial burden of engaging independent auditors to verify the accuracy of the exemption is not consistent with other sections within the TGA which accept self-declarations and assurances during the premarket assessment and lifecycle management of products.

Option 2: Retain the LVT scheme, with some amendments to improve its efficiency

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.
2. What do you see as the broader benefits of this option?
3. What do you see as the drawbacks of this option?
4. If you could improve the way the LVT scheme operates, what changes would you introduce?

1) J&J supports this option in general with some changes as follows:
    a. Support amendments that would improve the scheme's administration and efficiency for both sponsor and the TGA.
    b. Do not support a scheme with a primary intent of supporting small business but rather provides for the supply of unique therapeutic goods which are of low financial value or not marketed.
    c. Support acceptance of self-declaration of financial data but for all sponsors regardless of business size.
    d. Support removing the annual cap. Whilst this recommendation would reduce the financial incentive for our business, J&J sees this as an acknowledgement of the need for an appropriate cost recovery model and a way of aligning the LVT scheme with the Cost Recovery Guidelines[2].

2) J&J sees that the broader benefits of the proposed model in Option 2 are:
    a. A reduction in administrative burden for sponsors.
    b. The self-declaration of actual turnover removes the financial burden from sponsors to obtain a third party audit/declaration.

3) J&J sees that the proposed model has a number of drawbacks which include, but are not limited to:
    a. The primary intent to support small business increases costs to larger businesses through cross-subsidy of annual charges. Arguably, post-market activities should be risk based and annual fees charged accordingly regardless of business size.
    b. Removing the cap will increase application costs and removes the incentive to claim an exemption on Class I medical devices.

[2] Australian Government Cost Recovery Guidelines July 2005 (the Guidelines) <http://www.finance.gov.au/publications/finance-circulars/2005/docs/Cost_Recovery_Guidelines.pdf>

4) J&J wish to suggest the following improvements to this option:
    a. Acceptance of the self-declaration should be for all businesses regardless of turnover. Declarations (e.g. S26A declarations) and other assurances are provided to the TGA without the need for independent auditing. An LVT declaration should be considered in the same manner and not require an independent auditor.
    b. To reflect true cost recovery principles, annual charges should not be levied until a product is marketed in Australia (see also Option 3, response 1).

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

Issues relating to Option 3

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

1) In principle, J&J does support this option; however there is a need to clarify that zero turnover does not always indicate that the goods are not supplied in Australia (e.g. Loaner capital equipment and orthopaedic instruments).
    a. J&J recommends that an option of assigning a status on ARTG entries in eBS which allows sponsors to indicate whether an entry is marketed/supplied or not marketed/not supplied. Annual charges would be applied to marketed entries only. This option addresses the need to keep currently inactive entries on the ARTG until such time the good is launched in the Australian market. An LVT exemption could still be claimed on products with low turnover but this would remove the non-marketed/supplied products from the annual invoice upfront.

2) It is difficult to estimate the business impact for J&J without further clarification on whether this option would only cover those goods not supplied in Australia or whether it would be all goods with zero turnover. Further detail around the proposed reduction in annual charges would also be required to make an assessment of the financial impact on the J&J business.

2) J&J suggests that such a scheme may have a supply impact:
    a. Sponsors may consider cancelling ARTG entries with zero or low turnover that still require supply. J&J believes it has a responsibility to provide products, at no cost, to a number of patients. If the LVT scheme was removed this would disadvantage patients benefiting from this supply.

3) J&J sees the potential benefits of the proposed scheme under this option:
    a. Potential of reduced annual charges.
    b. Reduced administrative burden of 'not marketed/not supplied' declaration for both TGA and sponsors should the TGA adopt the recommendation given under point 1.
    c. Able to maintain inactive ARTG entries pending launch without cost as they are not incurring any post marketing costs to TGA, similar to export only products which do not currently incur an annual fee.

4) J&J considers the drawbacks for the proposed option as being:
    a. Assumes zero turnover is the same as not supplied, therefore no exemption for goods supplied free of charge (e.g. loaner capital equipment)
    b. This option does not provide for essential therapeutic goods for small patient populations.

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

Issues relating to Option 4

1. Do you support the option of confining eligibility of annual charge exemptions to small business?
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.
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.
4. What do you see as the broader benefits of this option?
5. What do you see as the drawbacks of this option?

1) J&J does NOT support an option that that only allows for small business to apply for LVT exemptions**.** This proposal can be considered as being anticompetitive as innovator or larger business will be required to subsidise the post market activities of products marketed by small business. Arguably, the level of post market activities required is dependent on the product and risk, rather than the size of business of the sponsor.

2) Implementation of this option will have a significant financial impact as J&J will not be able to claim any annual charge exemptions (figures indicated under Option 1), for the same products marketed by small business.

3) J&J would like to highlight the fact that a number of large businesses provide unique (and often very expensive) therapeutic products for rare medical conditions. The supply of these products is often not for commercial reasons but for ethical reasons. J&J is of the opinion that it is in the best interest of public health that these products remain on the ARTG.

4) J&J sees limited benefit in the proposed model. Whilst there is intent to benefit small business, there is additional financial burden on other businesses to subsidise the post-market activities required for products manufactured by small business.

5) J&J is of the opinion that there are several drawbacks to this option:
    a. The cost of post-market activities will be subsidised by sponsors who do not meet the small business definition.
    b. Low volume unique products sponsored by larger business will no longer be exempt from annual charges.

Option 5: Cease the LVT scheme completely.

Issues relating to Option 5

1. Do you support the cessation of the LVT scheme? Please detail why you hold this view.
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.
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.
4. What do you see as the broader benefits of this option?
5. What do you see as the drawbacks of this option?

1) J&J does not support the cessation of the LVT scheme completely. J&J is of the view that the scheme provides a public health benefit as it supports sponsors who supply low value goods that meet an essential clinical need. Additionally, having an LVT system is in line with the cost recovery model, where products that are not supplied will have minimal post market surveillance and compliance monitoring.

3) In the first year, it is unlikely that there would be a discontinuation of supply of products. This may need to be reassessed at a later stage and during further consultation.

4) J&J is concerned that there is no real benefit in the abolition of the LVT scheme.

5) The major drawback as viewed by J&J is that the supply of therapeutic products for rare medical conditions may be compromised. Compassionate use schemes may cease to exist as additional financial pressure is put on sponsors as a result.

Overall Preferred Option

J&J would like to propose an option that is a combination of a number of key elements of options 2 and 3. This is in line with the Cost Recovery Guidelines as required.

1) Annual charge exemptions for therapeutic goods through both of the following processes:
   a) Charged according to marketing status – goods not supplied in the Australian market as indicated by ARTG entry status (declared by the sponsor) will not attract annual charges.
   b) Low value but meet an essential clinical need - based on low turnover self-declaration.

2) Reduced administrative burden by accepting self-declaration of marketing status and financial data from all businesses, regardless of turnover.

3) Removing the annual cap to promote fairness and consistency with Cost Recovery Guidelines.

Conclusion

J&J would like to thank the TGA for the opportunity to comment on the review of the Low Value Turnover Exemption Scheme. J&J trust that the response that has been provided is of assistance and looks forward to further collaboration to develop a mutually agreeable program of regulatory reform.