Submission No. 8

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Regulatory Integrity Section
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Review of the Low Value Turnover Exemption Scheme (LVTES)

This submission is made on behalf of the Australian Food and Grocery Council (AFGC) in response to the Therapeutic Goods Administration's April 2014 Consultation Paper "*Review of the low value turnover exemption scheme*". The AFGC is the leading national organisation representing Australia's food, drink and grocery manufacturing industry, comprising more than 180 companies, subsidiaries and associates which constitutes in the order of 80 per cent of the gross dollar value of the processed food, beverage and grocery products sectors.

[1] General Comments

The Consultation Paper identifies that annual charges on entries in the Australian Register of Therapeutic Goods are levies to recover the TGA's costs of post-market regulatory activities such as the monitoring of product safety and monitoring sponsor compliance with regulatory obligations.

The AFGC understands that the cost-recovery basis for such activities is not within the scope of this consultation, but nonetheless the regulatory functions funded through the levy are an important consideration in determining how the levy should operate, including when considering the policy and operation of the LVTES. Cost recovery is not an opportunity to raise funds generally, but is limited to recovering the costs of specific functions provided to the industry as a whole. Consequently, it is wrong to apply the levy, for example, in relation to products in respect of which no post-market surveillance actually takes place.

The further issue is that of efficiency and red tape reduction. The agency costs of recovering a levy, or the sponsor costs in complying with the levy, should not be disproportionate to the revenue raised. There is somewhat of a reflection of this in

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the nature of the current LVTES, which exempts from payment ARTG products where the turnover value is less than 15 times the annual charge (in effect capping the levy at about 6.7%).

This submission considers the Consultation Paper reform options in light of these criteria: the relationship between levy and activity, levy efficiency and compliance costs and complexity.

[2] Comments on the Review Options

Option 1 is not supported for the reasons identified in the Consultation Paper – the current arrangement is unnecessarily complex and costly in compliance, to the point where compliance costs can exceed the value of the exemption.

Option 2 is the preferred option, with some modification. The option proposes four reforms for the LVTES. These are considered appropriate with one variation, and with the addition of a further reform –

(a) The proposal to allow small businesses to self-declare sales turnover without external audit should be extended to all sponsors. No evidence has been provided that small businesses are inherently more honest than larger enterprises, and given the greater surveillance on company accounts faced by larger corporations, it seems unlikely to be the case. Self-assessment without external audit should be the case for all businesses, subject of course to a requirement to provide substantiation on request.

(b) Annual fees for new products should be payable from time of first marketing, not from time of registration. This would preclude post-market surveillance levies being imposed in relation to products not actually on the market, and reduce compliance costs through the avoidance of nil returns (especially where the nil return requires independent auditing).

(c) For clarity, the levy should continue to be applied on the basis of domestic sales only, with all export sales being excluded.

The AFGC sees this modified option as closely aligning with the recommendations of the which it supports.

Option 3 is not supported. It does have the advantage of not placing a levy for post-market surveillance on products not supplied on the Australian market, and this feature should be incorporated into the preferred option. However, it does not address the issue of compliance costs versus revenue for low value transactions within Australia,

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Yours faithfully
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