

Submission No. 32



Regulatory Integrity Section
Therapeutic Goods Administration
136 Narrabundah Lane
Symonston ACT 2609

Via email: ltconsultation@tga.gov.au

17 June 2014

Dear Sir/ Madam

Thank you for the opportunity to provide feedback on the Therapeutic Goods Administration's Review of the Low Value Turnover (LVT) Exemption Scheme.

Medicines Australia represents the research-based pharmaceutical industry in Australia, which brings new medicines, vaccines and health services to the Australian market. Our industry has the potential to be one of the key innovative industries for Australia's future, but the policy environment in both business and health policy must be supportive of industry for this to occur.

Medicines Australia believes that, while the relative merits of the current LVT scheme will vary for individual companies, there is a need for a scheme to support low volume, low turnover products in the Australian regulatory system for prescription medicines.

Medicines Australia acknowledges that the current LVT scheme predates the introduction of full cost recovery of regulatory functions and may therefore not be entirely current in the context of the principles of the cost recovery policy. As indicated in the consultation paper, fee exemptions under the LVT scheme result in distortion of annual charges. Therefore, the current scheme may need to be adapted to deliver appropriate cost recovery for regulatory activities undertaken by the TGA and additional provisions to better support small businesses may be needed.

Medicines Australia agrees that the current process for applying for an exemption under the LVT scheme is administratively burdensome. Any amendments to the scheme should significantly reduce the administrative burden for the TGA and industry. This may include streamlining of the exemption administration process, including elimination of third party certification requirements.

Overall, any revisions to the policy framework should improve the efficiency of the current LVT scheme, reduce the administrative burden and provide support for Australian business in a competitive global market.

If you wish to discuss any of these comments further, please contact

would welcome the opportunity to discuss this with you further.

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