



Australian Government

Department of Health
Therapeutic Goods Administration

Mr Jason McNamara
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
1 National Circuit
BARTON ACT 2600

Email: helpdesk@obpr.gov.au

Dear Mr McNamara

Regulation Impact Statement –final assessment second pass

I am writing in relation to the attached Regulation Impact Statement (RIS) prepared for the Low Value Turnover (LVT) Exemption Scheme. The regulatory burden to business, community organisations and/or individuals has been quantified and offsets have been identified and quantified using the Regulatory Burden Measurement framework. These have been agreed with your office.

I am satisfied that the RIS addresses the three key comments raised by your office and notified by Mr Tony Simovski in his letter of 27 February 2015:

- The RIS states the reasons that consultation options 2 and 4 were not considered to be feasible options for achieving the Government's objectives and how these conclusions were made.
- The RIS explicitly discusses the impact of each RIS option on small businesses.
- The RIS provides a description of the proposal's development at each major decision point.

Accordingly, I am satisfied that the RIS now meets best practice consistent with the *Australian Government Guide to Regulation*.

I submit the RIS to the Office of Best Practice Regulation for formal final assessment.

Yours sincerely

Adj Professor John Skerritt
National Manager, Therapeutic Goods Administration
Deputy Secretary, Department of Health

13 March 2015