Australian Government
Department of the Prime Minister and Cabinet
Office of Best Practice Regulation

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

Dear Professor Skerritt

Final Regulation Impact Statement – Low Value Turnover (LVT) Exemption Scheme

Thank you for forwarding the Regulation Impact Statement (RIS) for the above proposal, which was received by the Office of Best Practice Regulation (OBPR) for final assessment on 19 March 2015. I note that you have formally certified the RIS as required by the best practice regulation requirements.

The proposal seeks to make amendments to the LVT Exemption Scheme in order to better align the scheme with the Government's Cost Recovery Guidelines, and to reduce the administrative complexity of the scheme. The most significant change to the scheme is that exemptions from paying the annual regulatory charge will only be granted for Register entries which are yet to commence turnover, compared with the current situation which allows exemptions for Register entries with turnovers less than 1.5 times the value of the annual charge.

The changes are estimated to result in a reduction in administrative costs of approximately $3 million per annum, and reduce the cross subsidy between those register entries that qualify for the exemption and those that do not.

The Office of Best Practice Regulation (OBPR) assesses RISs for consistency and adequacy – consistency relates to following the prescribed process and adequacy relates to the quality of the analysis.

I note the agency has been consistent with the RIS guidelines, having twice provided a certified RIS (addressing all seven elements) to the OBPR for final assessment before the decision-maker considers the RIS.

I also note that the RIS is adequate as it does not contain obvious errors and has a degree of detail and depth of analysis that is commensurate with the magnitude of the problem and the size of the potential impact of the proposal. In addition, the regulatory cost estimates have been agreed with the OBPR.

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

For legislation which is tabled in the Parliament, a copy of the RIS must be included in the explanatory memorandum (for primary legislation) or the explanatory statement (for legislative instruments). Please ensure that your officers provide the OBPR with a copy of (or link to) the explanatory memorandum or explanatory statement when these are made public.

Additionally, the OBPR maintains a RIS website and RISs are published as soon as practicable following a regulatory decision being publicly announced. We would appreciate you advising us when a decision on this proposal is announced, and forwarding a final copy of the RIS in *Microsoft Word .doc* format in a form meeting the Australian Government's *Web Content Accessibility Guidelines*. We suggest liaising with your web services team to ensure these guidelines are met. The OBPR should be consulted if the RIS is amended. It is the agency preparing the RIS, not the OBPR, which is responsible for the content of the published RIS.

The website provides a public comment facility on RISs posted on the site. The OBPR moderates this facility for offensive content but does not moderate debate.

Please retain this letter as a record of the OBPR's advice. Our reference number for this issue is 17309. If you have any further queries, please do not hesitate to contact me.

Yours sincerely

Tony Simovski
A/g Deputy Executive Director
26 March 2015