



Australian Government

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

Reference: 20860
Telephone: 6271 6270
e-mail: helpdesk-obpr@pmc.gov.au

Adj. Professor John Skerritt
Deputy Secretary
Health Product Regulation Group
Department of Health

via email

Dear Prof Skerritt

Regulation Impact Statement – Final Assessment – General requirements for labels for medicines

Thank you for your letter of 1 July 2016 submitting the final assessment Regulation Impact Statement (RIS) for the above proposal to the Office of Best Practice Regulation (OBPR). I note that the RIS has been formally certified at the Deputy Secretary level consistent with best practice.

The OBPR's final assessment is that the Department of Health is compliant with the Government's RIS requirements and the RIS is consistent with best practice. Given the expected magnitude of the impacts of the proposal, the OBPR considers the level of analysis in the RIS is consistent with best practice.

This assessment is based on:

- the regulatory burden costings have been agreed with the OBPR; and
- your letter of 1 July 2016 certifying the RIS responds to the OBPR's formal comments on the RIS submitted for first-pass assessment.

Publication requirements

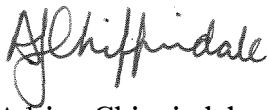
The OBPR maintains a RIS website and aims to post RISs as soon as practicable after the regulatory decision has been publicly announced. We would appreciate you advising us when a decision on this proposal is announced, and forwarding a final copy of the RIS in *Microsoft Word .doc* format in a form 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 matter is 20860. If you have any further queries, please do not hesitate to contact me.

Yours sincerely

A handwritten signature in black ink, appearing to read 'A Chippindale', written in a cursive style.

Adrian Chippindale
A/g Deputy Executive Director
Office of Best Practice Regulation
5 July 2016