



Australian Government

Department of Finance and Deregulation Office of Best Practice Regulation

Reference: 12675
Contact: Paul Britt
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Dr Anthony Hobbs
A/g National Manager
Therapeutic Goods Administration

Re: Required Advisory Statements for Medicine labels (RASML)

Dear Mr Hobbs

Thank you for forwarding the draft Regulation Impact Statement (RIS) received by my office on 17 May 2013.

The RIS contains an adequate level of analysis and meets the Government's best practice regulation requirements. We note that the RIS has been formally certified at the equivalent Deputy Secretary level as required by the best practice regulation requirements.

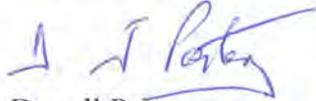
The Government's *Best Practice Regulation Handbook* (June 2010), at paragraph 2.37, requires that for regulation which is tabled in the Parliament, a copy of the adequate RIS is included in the explanatory memorandum (for primary legislation) or the explanatory statement (for legislative instruments). Would your officers please provide the OBPR with a copy of (or link to) the explanatory memorandum or explanatory statement when these are made public.

Additionally, the Office of Best Practice Regulation (OBPR) maintains a RIS website and the Government requires that RISs be posted within 5 business days of 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 12675. If you have any further queries, please do not hesitate to contact me.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'D. J. Porter', with a stylized flourish at the end.

Darrell Porter
Deputy Executive Director
Office of Best Practice Regulation
24 May 2013