



Australian Government

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

Reference: 14631
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Professor John Skerritt
National Manager
Therapeutic Goods Administration
Department of Health

Dear Professor Skerritt

Final Assessment Regulation Impact Statement – new regulatory framework for in-vitro diagnostic devices

Thank you for forwarding the Regulation Impact Statement (RIS) for the above proposal for final assessment on 26 May 2014. I note that you have formally certified the RIS as required by the best practice regulation requirements.

The Office of Best Practice Regulation's (OBPR) final assessment is that the Therapeutic Goods Administration is compliant with the Government's requirements. This assessment reflects:

- that the estimated impact on regulatory costs has been agreed with the OBPR; and
- your letter dated 23 May 2014 (received 26 May 2014) certifying that the RIS responds to the OBPR's formal assessment of the RIS on 12 March 2014. In particular, your letter indicates that additional information is provided in the RIS relating to background, the description of the regulatory proposals, the impact analysis, and changes were made to the document to better reflect the new current best practice regulation requirements.

In addition, I note that the RIS does not contain obvious errors, and provides a good basis on which to make a final decision on this matter.

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 14631. If you have any further queries, please contact me.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'D. T. Porter', with a long, sweeping horizontal line extending to the right.

Darrell Porter
Deputy Executive Director
Office of Best Practice Regulation
2 June 2014