



Australian Government

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

Reference: 17059
Telephone: 6271 6270
Email: helpdesk@obpr.gov.au

Prof John Skerritt
National Manager
Therapeutic Goods Administration

Dear Prof Skerritt

Final Assessment of Regulation Impact Statement – Premarket assessment requirements for Australian manufactured medical devices

Thank you for forwarding the Regulation Impact Statement (RIS) on the above matter for final assessment on 1 October 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 Department of Health is compliant with the Government's RIS requirements and is consistent with best practice. This assessment is based on:

- the Department undertaking an open consultation process, informed by RISs formally submitted to the OBPR;
- the annual regulatory cost savings for the options presented having been agreed with the OBPR;
- the Department having twice submitted the certified RIS for the OBPR's assessment prior to a final decision being taken; and
- your letter of 1 October 2014 certifying that the RIS responds to the OBPR's formal comments of 17 September 2014.

In addition, I note that the RIS: addresses the seven RIS questions; does not contain obvious errors; and considers a minimum of three policy options, one of which is a less regulatory option.

The OBPR also notes that the recommended option – allowing third party conformity assessment for the majority of medical devices and in-vitro diagnostic devices regardless of where they are manufactured – has the potential to reduce overall compliance costs for Australian manufacturers of these products.

The OBPR maintains a RIS website and aims to post RISs as soon as practicable after the regulatory decision has been publicly announced. To assist with this, 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 OBPR website provides a public comment facility. 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 17059. If you have any further queries, please do not hesitate to contact me on 6271 6286.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Tony Simovski', with a long horizontal stroke extending to the right.

Tony Simovski
A/g Deputy Executive Director
2 October 2014