Australian Government
Department of Health
Therapeutic Goods Administration

Mr Jason McNamara
Executive Director
Office of Best Practice Regulation
Department of the Prime Minister and Cabinet
1 National Circuit

BARTON ACT 2600
Email: helpdesk@obpr.gov.au

Dear Mr McNamara

Regulation Impact Statement –final assessment second pass

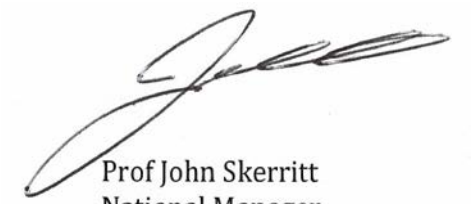
I am writing in relation to the attached Regulation Impact Statement (RIS) prepared on premarket assessment requirements for Australian manufactured medical devices. The regulatory burden to business, community organisations and/or individuals has been quantified and offsets have been identified and quantified using the Regulatory Burden Measurement framework. These have been agreed with your office.

I am satisfied that the RIS addresses the concerns raised in your letter of 17 September 2014. Specifically, your Office suggested two minor changes:

- In order to clarify the (changing) nature of the problem, the RIS could illustrate whether the number of certifications issued by the Therapeutic Goods Administration (TGA) as a proportion of the Australian medical device market has considerably changed over time. This may also assist in providing a better context for the discussion on public health and safety in the impact analysis.
- The RIS consistent with the regulatory costings prepared by TGA and agreed to by the OBPR, should note and explain any regulatory costs incurred overseas by domestic manufacturers are considered business as usual as almost all Australian manufacturers obtain this certification currently.

These suggestions have now been incorporated into the RIS at pages 8 and 14 respectively. Accordingly, I am satisfied that the RIS now meets best practice consistent with the *Australian Government Guide to Regulation*.

I submit the RIS to the Office of Best Practice Regulation for formal final assessment.
Yours sincerely



Prof John Skerritt
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1 October 2014

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TGA Health Safety Regulation