



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

Mr Jason McNamara  
Executive Director  
Office of Best Practice Regulation  
Department of Prime Minister and Cabinet  
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Reference: ID 14631

Dear Mr McNamara

**Second Formal Version Regulation Impact Statement – final assessment**

I am writing in relation to the attached Regulation Impact Statement (RIS) prepared by the Therapeutic Goods Administration (TGA) for amendments to the new regulatory framework for IVDs.

I am satisfied that the second formal version of the RIS addresses the concerns raised in your letter of 12 March 2014. Specifically, additional information has been provided in the RIS on the following:

1) Background

An additional section under the title of 'IVD market in Australia' has been included and provides background information on:

- the categories and numbers of IVDs
- the number of local manufacturers and the proportion of local versus imported IVDs

2) Proposals

The proposal to address Issue 1 on page 13 has been reworded to clarify that although not required to be included in the RIS, the proposed extension to the timeframe is expected to have a beneficial impact on industry and health outcomes.

3) Impact Analysis

Further information has been included in the impact analysis that expands on the likely impacts of the proposed changes on the risks to individual and population health and how the changes manage these risks.

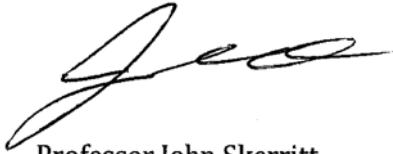
4) New RIS requirements

Changes have been made in the introduction (page 4) and consultation section (page 11) to reflect the terminology now used under the new RIS requirements.

Accordingly, I am satisfied that the second formal version of the RIS now meets the Government's best practice regulation requirements.

I submit the second formal version of the RIS to the Office of Best Practice Regulation for final assessment.

Yours sincerely

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

Professor John Skerritt  
National Manager

23 May 2014