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 for the International Harmonisation of Ingredient Names project. 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 by your office and notified by Mr Tony Simovski in his letter of 24 April 2015:

- The RIS provides further information on the scale of the problem, including issues for consumers travelling with medicines, the size of the market and the barriers to international trade.
- The RIS discusses the difference between voluntary adoption of the new ingredient names (Option 5) and the status quo (Option 1).
- The RIS further analyses the economic costs and benefits of the proposed options, including quantified estimates, where possible, and information on the anticipated impact on consumers and healthcare professionals.

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

Adjunct Professor John Skerritt
National Manager
Therapeutic Goods Administration
27 ~~June~~ May 2015

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