



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Mr Jason McNamara
Executive Director
Office of Best Practice Regulation
Department of Finance and Deregulation
John Gorton Building
King Edward Terrace
PARKES ACT 2600

Email: helpdesk@obpr.gov.au

Dear Mr McNamara

Regulation Impact Statement – update to the *Required advisory statements for medicine labels (RASML)*


I am writing in relation to the attached draft Regulation Impact Statement (RIS) prepared by the Therapeutic Goods Administration for the proposal to update the *Required advisory statements for medicine labels (RASML)* to include new and amended mandatory advisory statements.

I am satisfied that the draft RIS meets the Government's best practice regulation requirements, in particular that:

- the problem being addressed and the objectives of government action are well articulated;
- all feasible options are considered;
- the analysis of the likely impacts of each option is adequate and presented in a balanced way; and
- the conclusion is supported by the analysis in the RIS.

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

Yours sincerely,


Dr Anthony Hobbs
A/g National Manager

15 May 2013