Australian Government

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

Reference: 19024
Telephone: 6271 6270
e-mail: helpdesk-obpr@pmc.gov.au

Adjunct Professor John Skerritt
National Manager
Therapeutic Goods Administration

cc: Health Deregulation Unit

Via email

Dear Professor Skerritt

Regulation Impact Statement – Second-pass final assessment – International Harmonisation of Ingredient Names

Thank you for submitting the Regulation Impact Statement (RIS) for the above proposal to the Office of Best Practice Regulation (OBPR) for second-pass final assessment on 28 May 2015. I note that the RIS has been formally certified at the Deputy Secretary level consistent with best practice.

The OBPR's final assessment is that the Therapeutic Goods Administration (TGA) is compliant with the Government's RIS requirements and the RIS is consistent with best practice.

This assessment is based on the fact that our comments of 24 April 2015 on the first-pass RIS have been appropriately addressed, and the TGA has been consistent with the RIS guidelines, having twice provided a certified RIS to the OBPR for assessment before the decision-maker considers the RIS. In addition, the regulatory impacts have been agreed with the OBPR, the RIS addresses the seven RIS questions and it does not contain obvious errors.

The RIS notes that the preferred option would increase the alignment of Australian ingredient names with international terminology by dealing with many of the identified inconsistencies. The RIS estimates the net regulatory cost of this option at $0.13m per annum. The originally proposed transition period has been lengthened, as suggested by stakeholders during consultation, which has the effect of lowering compliance costs. The RIS explains that this cost is expected to be offset by other gains, such reduced risk of incorrect use of medicines and increased clarity for patients and healthcare providers. The RIS concludes that this option will result in a small reduction in barriers to trade for individual companies, but is unlikely to have a noticeable effect on the overall market.

The OBPR maintains a RIS website and the Government requires that RISs be posted as soon as practicible after the regulatory decision is publicly announced. 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 website provides a public comment facility on RISs posted on the site. 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 matter is 19024. If you have any further queries, please do not hesitate to contact me.

Yours sincerely

Jason McNamara
Executive Director
Office of Best Practice Regulation
3 June 2015