



Australian Government

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

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Adjunct Professor John Skerritt  
Deputy Secretary  
Health Products Regulation Group  
Department of Health

Dear Professor Skerritt

**Regulation Impact Statement – Second Pass Final Assessment –  
Proposal to clarify that certain sports supplements should be regulated as  
therapeutic goods**

Thank you for your letter submitting a Regulation Impact Statement (RIS) on the above proposal to the Office of Best Practice Regulation (OBPR) for Second Pass Final Assessment on 17 July 2020. I have appreciated the Department's constructive engagement during the development of the RIS.

The RIS addresses the seven RIS questions and follows an appropriate policy development process commensurate with the significance of the problem and magnitude of the proposed intervention. While the RIS could have further drawn out the incremental differences in costs and benefits of the options considered, it explains the risks and potential consequences of the current arrangements, the rationale for the proposed reforms, and the likely impacts including the pathways for industry compliance.

I also note the scope of the proposal was refined, acknowledging initial stakeholder concerns, and reflects a considered approach to mitigating the current safety risks. The OBPR's assessment is that the Australian Government RIS requirements have been met and the analysis in the RIS is consistent with good practice. The RIS may now be provided to the decision-maker to inform a final decision.

We would appreciate you advising us when a final decision has been announced and forwarding a copy of the RIS in a form meeting the Government's accessibility requirements. The OBPR will publish the RIS, along with your certification and this assessment, on the OBPR's website at <https://ris.pmc.gov.au>.

If you have any further queries, please do not hesitate to contact me.

Yours sincerely

Jason Lange  
Executive Director  
24 July 2020