

Department of the Prime Minister and CabinetOffice 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 prevent the uptake of nicotine containing e-cigarettes by ever users (adolescents and young adults), to support smoking cessation and to reduce nicotine poisonings of children

Thank you for your letter of 15 December 2020 submitting a Regulation Impact Statement (RIS) on the above proposal for Second Pass Final Assessment. I note the RIS has been formally certified at the Deputy Secretary level consistent with the *Australian Government Guide to Regulatory Impact Analysis*.

I have appreciated the Department's constructive engagement during the RIS's development.

I acknowledge the challenge of obtaining reliable data where market actors may be reluctant to fully disclose their activities given the existing illegality of domestic trade and, in most jurisdictions, possession of e-cigarettes with nicotine. While the RIS would have benefited from even deeper analysis of potential market behaviour and could have better integrated the issue of product standards into the policy options considered, it clearly explains the rationale for the proposed reform, analyses the likely first order impacts, and makes balanced and transparent judgments based on the available body of evidence.

Given this, the Office of Best Practice Regulation's (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 addresses the seven RIS questions and follows a policy development process commensurate with the significance of the problem and magnitude of the proposed intervention.

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 17 December 2020