



Australian Government

Department of Health and Aged Care

Deputy Secretary

Ms Joanna Abhayaratna
Executive Director
Office of Impact Analysis
Department of the Prime Minister and Cabinet
BARTON ACT 2600
Email: Helpdesk-OIA@pmc.gov.au

Dear Ms Abhayaratna

Subject: Impact Analysis - Proposed adoption of the Australian Sunscreen Exposure Model (ASEM) - Second Pass Final Assessment (OIA24-07792)

I am writing in relation to the attached Impact Analysis (IA) prepared for adoption of the Australian Sunscreen Exposure Model (ASEM) by the Therapeutic Goods Administration (TGA). The ASEM will be used for assessing the safety of sunscreen ingredients that align with Australian conditions and consumer practices.

I am satisfied that the revised IA addresses the concerns raised in your letter of 21 October 2024. Specifically, further information has been added to strengthen the relevant questions, as below:

- details about different international and domestic approaches for assessing sunscreen exposure
- comparison of methodologies used in Europe
- the main objectives of government intervention
- SMART goals framework
- why government intervention is needed
- alternatives to government intervention
- success metrics included
- details of alternative options considered
- information on distributional impacts, regulatory burden estimates, and competition and regulation

- net benefit based on qualitative analysis
- consideration of regulatory costing by providing hypothetical scenarios
- implementation risks, risk rating and mitigation measures
- impact analysis decision points
- evaluation plan.

Due to data limitations, regulatory burden estimates have been calculated based on hypothetical scenarios. In addition, a qualitative net benefit analysis has also been conducted to compare the net benefits of each option.

Accordingly, I am satisfied that the IA is now consistent with the 6 principles for Australian Government policy makers as specified in the *Australian Government Guide to Policy Impact Analysis*.

I submit the IA to the Office of Impact Analysis for formal final assessment.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Anthony Lawler', with a long horizontal stroke extending to the right.

Professor Anthony Lawler
Health Products Regulation Group

29 November 2024