

Australian Government

Department of Health and Aged Care

Deputy Secretary

Mr Daniel Craig A/g Executive Director Office of Impact Analysis Department of the Prime Minister and Cabinet 1 National Circuit BARTON ACT 2600

Email: helpdesk-OIA@pmc.gov.au

Dear Mr Craig

Subject: Impact Analysis – Proposed adoption of the Australian and New Zealand Sunscreen Standard AS/NZS 2604:2021 – Second Pass Final Assessment Reference: OIA23-05253

I am writing in relation to the attached Impact Analysis (IA) prepared for adoption of the Australian and New Zealand Sunscreen Standard (AS/NZS 2604:2021) (the 2021 Sunscreen Standard) into therapeutic goods legislation.

I am satisfied that the IA addresses the concerns raised in your letter of 5 January 2024. Specifically, information has been added to strengthen the relevant questions as below:

- trend data for skin cancer rates
- sunscreen usage by Australians
- the structure of the sunscreen sector in terms of peak bodies, range of businesses
- a statement on what success would look like in terms of the adoption of the standard
- links to Government objectives and the ability of the options to meet those objectives
- benefits of retaining the 2012 standard included in the status quo
- details on the key testing laboratory in Australia and the potential for broader supply chain impacts

- key quotes from the public consultation submissions in benefits and disadvantages of each option
- links back to how the preferred option meets Government objectives
- roles and responsibilities of stakeholders in implementation
- implementation risks and consequences
- detail on the proposed evaluation approach, responsibilities of stakeholders, key dates and objectives.

No regulatory cost savings could be identified that were directly related to this proposal. However, by allowing a 5-year transition period for sponsors to comply with the new standard there will be adequate time to manage existing stock and limit regulatory burden. In addition, requiring Australian therapeutic sunscreens to comply with the accepted international standards for testing sunscreens will increase consumer confidence in these products and strengthen the international reputation of the Australian sunscreen industry.

Accordingly, I am satisfied that the IA is now consistent with the six 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

Professor Anthony Lawler Health Products Regulation Group

30 January 2024