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Mr Terry Slater
National Manager
TGA
PO Box 100
Woden, ACT 2606

Dear Mr Slater,

RE: Review of the regulation of products at the interface between cosmetics and therapeutic goods; specifically sunscreens

I refer to the Draft Discussion Paper posted by the TGA in relation to the above review and the invitation for comment. I have examined in detail the material included in the Discussion Paper and set out my comments below.

By way of background to the comments that I make, I currently hold the position of Senior Lecturer in Dermatology at the University of Sydney, which entails research on the photobiology of human skin as well as clinical dermatology practice at Royal Prince Alfred Hospital. I am a member of the NSW Cancer Council Skin Cancer Reference Group, and am the Australasian College of Dermatologists representative on the Australian and New Zealand Standards Committee for Sunscreen Agents. The comments that I set out here are however my own and are not intended to represent the views of these organisations.

Sunscreens are therapeutic agents with proven efficacy in the prevention of premalignant lesions (actinic keratoses), non-melanoma skin cancers, photo-ageing, UV-induced immunosuppression and sunburn. As a result of continuing public education campaigns, Australian consumers are increasingly aware of the importance of regular sunscreen use, not only during intense UV exposure but also in the context of their everyday activities. For adults in this country, this "incidental" UV exposure comprises a large proportion of cumulative annual exposure. Although this lower intensity exposure is less likely to result in sunburn, many adverse effects of UV exposure occur at suberythral levels. Moreover, most "incidental" UV exposure is to the face, the area most at risk for nonmelanoma skin cancers and actinic keratoses and the area where treatment of these lesions entails the highest morbidity and the highest cost. Sunscreens thus play an important role whether used for protection from acute, intense UV exposure or from ongoing, incidental exposure.

Increased public comprehension of the meaning of sun protection factor (SPF) numbers, and the relative efficacy of products with different SPFs, means that any product labelled with an SPF should be tested, quality-controlled and regulated in the same way, regardless of the presence of emollients in the preparation and regardless of its water resistance or otherwise. A consumer choosing an SPF labelled emollient over an agent without sunscreens properties should be able to do so on the basis that the product is consistent with other sunscreen

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products and accordingly offers reliable UV protection. Further, sunscreens labelled 20+ are currently classified as “high protection,” encouraging consumers to expect more than incidental sun protection from any product so labelled, regardless of whether the labelling refers to skin cancer prevention or not.

Hence both “primary” and “secondary” sunscreens are intended for important therapeutic purposes. The position of moisturisers containing sunscreens in the Australian market cannot but include their UV protective effects as a central marketing feature. Hence all sunscreen products with labelled SPF should be included in the therapeutic goods register. As the Discussion Paper states, sunscreens with $SPF < 4$ cannot be expected to provide significant UV protection; hence these products should not be classed as sunscreens and should not carry SPF labelling.

In summary, it is my view that

- 1. Primary sunscreens where $SPF \geq 4$ should be classed as therapeutic products and described as Class I medicines, as per the Discussion Paper**
- 2. Primary sunscreens where the SPF is < 4 should not be classified as therapeutic products, and should not carry SPF labelling.**
- 3. Moisturisers that contain a sunscreen and carry SPF labelling in Australia should be classed as therapeutic products.**

As acknowledged in the Draft, Australia exercises relatively minimal control over the manufacture of cosmetics, and the importance of skin cancer and sun protection in Australia means that products used to help reduce the public health burden of photodamage should be appropriately regulated as therapeutic products.

Yours sincerely,

Dr Diona Damian