



615, St Kilda Road,
Melbourne
Victoria
3004

10 May 2017

Dear Sir/Madam,

Re: Submission to the TGA consultation Options for Future Regulation of ‘Low Risk’ Products from the National Skin Cancer Committee of Cancer Council Australia

Cancer Council Australia (CCA) is the leading NGO for cancer research, information and support in Australia. CCA markets a range of sun protection products, including sunscreen.

CCA welcomes the opportunity to make this submission to the Therapeutic Goods Administration (TGA) on proposed options for the future regulation of “low risk” products (in this case, sunscreens, which are regulated as medicines). This submission is made on behalf of all Cancer Councils across Australian states and territories, which includes the SunSmart skin cancer prevention program.

Australia has one of the highest rates of skin cancer in the world. There is evidence that regular sunscreen use can reduce the incidence of invasive melanoma and squamous cell carcinoma.^{i,ii,iii} Sunscreen is used by 1 in 3 Australian adults when outdoors on summer weekends, which makes it one of the most common forms of sun protection.^{iv} This emphasises the importance of sunscreen efficacy. When the ultraviolet (UV) index reaches three and above, CCA recommends that SPF 30 (or higher) broad-spectrum, water-resistant sunscreen is used in combination with other sun protection measures (sun protective clothing, broad-brimmed hat, shade and sun glasses) as a last line of defence.

This submission relates to regulation of sunscreen products that make SPF claims (Options 1-3, 6) rather than ingredients (Options 4 & 5), consistent with CCA’s primary expertise. Of the options presented, CCA supports Option 1 – maintaining the status quo regulation of sunscreens. We believe it is important for sunscreens to be included in the Australian Register of Therapeutic Goods (unless exempt). We note concerns raised regarding the current model, particularly the perception that this process results in additional costs and delays to market. However, the high number of listable sunscreens (932) suggests these barriers are not excessive or insurmountable for manufacturers. CCA urges the TGA to retain the current high testing standards, which give consumers confidence that sunscreen purchased in Australia will meet therapeutic claims.

CCA has a number of concerns regarding Option 2. Although simplification of the current shared regulatory framework is desirable, it is important that this does not come at the expense of the safety and quality of sunscreens. CCA is concerned that the NICNAS reforms would compromise regulation of secondary sunscreens if the ACCC became the only regulatory body with oversight of these products. Regulation of secondary sunscreens by the ACCC alone (as also proposed in Option 6) would weaken consumer protection, as the onus of responsibility to make and substantiate product complaints would rest solely with consumers. CCA asserts that any product that makes an SPF claim should be regulated, as our experience has shown that industry self-regulation is undermined by conflict of interest. As such, CCA would only support Option 2 if NICNAS (or an equivalent regulatory body) continued to regulate secondary sunscreens that make SPF claims. In the absence of NICNAS or an equivalent

regulatory body, CCA believes Option 3 should be implemented together with Option 2 in order to prevent secondary sunscreens from making SPF claims.

CCA urges the TGA to place the health of consumers over industry profit by maintaining the status quo. Consumer concerns about allergic reactions, sunscreen use in infants and use of nanoparticles have received considerable media attention in recent years. In particular, consumer confidence in sunscreen was challenged last summer as a result of a viral social media post that led to a number of complaints about sunscreen, which received significant media attention. In that instance, the high standard of sunscreen regulation by the TGA helped to assure Australians that sunscreen products are safe and effective. Given that sunscreens have been estimated to reduce skin cancer incidence by 10-15% in Australia^v, this is an important public health outcome.

CCA appreciates the opportunity to contribute to this consultation. Please do not hesitate to contact us should you require any additional information or have in queries in relation to this submission.

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ⁱ Green AC, Williams GM, Logan V, Strutton GM. Reduced melanoma after regular sunscreen use: randomized trial follow-up. *Journal of Clinical Oncology* 2011; 29(3): 257-63.

ⁱⁱ Green A, Williams G, Neale R, Hart V, Leslie D, Parsons P, Marks GC, Gaffney P, Battistutta D, Frost C, Lang C, Russell A. Daily sunscreen application and betacarotene supplementation in prevention of basal-cell and squamous-cell carcinomas of the skin: A randomised controlled trial. *Lancet* 1999; 354(9180): 723-9

ⁱⁱⁱ van der Pols JC, Williams GM, Pandeya N, Logan V, Green AC. Prolonged prevention of squamous cell carcinoma of the skin by regular sunscreen use. *Cancer Epidemiology, Biomarkers & Prevention* 2006; 15(12): 2546-8.

^{iv} Volkov A, Dobbins SJ. 2013–14 National Sun Protection Survey: Report 2. *Sun protective behaviours and sunburn incidence on summer weekends among Australians in summer 2013–14 (unpublished)*. Centre for Behavioural Research in Cancer, Cancer Council Victoria: Melbourne, Australia, November 2014.

^v Olsen CM, Wilson LF, Green AC, Bain CJ, Fritschi L, Neale RE, Whiteman DC. Cancers in Australia attributable to exposure to solar ultraviolet radiation and prevented by regular sunscreen use. *Australian and New Zealand Journal of Public Health* 2015; 39(5): 471-6.