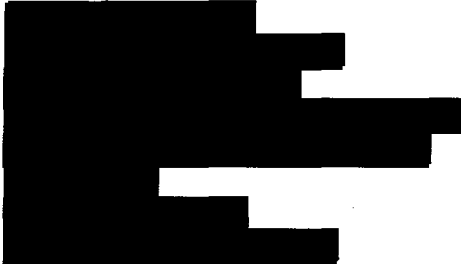


Date: 22 June 2010



RE: TGA Sunscreen Guidelines - Response to Consultation

Thank you for the opportunity to comment on Proposed revisions to Chapter 10 'Sunscreens' in the *Australian Regulatory Guidelines for OTC Medicines (ARGOM)*. This letter outlines the Cancer Institute NSW's role in the prevention of skin cancer in NSW, limitations to effective sunscreen use in preventing skin cancer and recommendations for improving sunscreen use under TGA regulations.

The Cancer Institute NSW is Australia's first government supported cancer control agency and was established in 2003 to reduce the burden of cancer in NSW. A priority for the Cancer Institute NSW is the prevention of cancer including skin cancer. Under the NSW Cancer Plan 2007-2010, the Cancer Institute NSW is committed to increasing public awareness of melanoma and skin cancer in order to prompt greater sun protection.

Skin cancers, including melanoma and non-melanomatous skin cancers, are more than five times the incidence of all other cancers combined, making them by far the most expensive cancers to treat in Australia.¹ Excluding non-melanomatous skin cancers, melanoma is the fourth most common cancer diagnosed in NSW and it is expected to rise in the future.²

Overexposure to Ultraviolet radiation (UVR) is responsible for almost all skin cancers. Despite being largely preventable, Australia has the highest rates of skin cancer in the world due to our geographical location, lifestyle, climate and a large fair skinned population. The most significant UVR exposure in Australia is due to the sun. UVR exposure can be reduced through the adoption of five sun protection measures, shade (natural and built), protective clothing, broad-brimmed hat, sunglasses and broad spectrum waterproof SPF30+ sunscreen (with reapplication every two hours).

The Cancer Institute has conducted both quantitative and qualitative research on attitudes and behaviours toward sun protection. Research found an overreliance on sunscreen as a means of protection from UVR, particularly among youth and young adults, and sunscreens are not used effectively to provide maximum protection. The Lifestyles and



Cancer Survey 2009 found pre-application of sunscreen to be sub-optimal with less than half (43%) of respondents always or often applying sunscreen before going outside. Nearly a quarter (22%) never pre-apply sunscreen. Reapplication of sunscreen every two hours is also problematic with over a third (34%) never reapplying and only a quarter (26%) always or often reapplying. In focus groups young people describe waiting to apply sunscreen after they notice their skin begin to show signs of overexposure and do not regularly reapply.

The revised guidelines are more comprehensive and should help improve the effective use of sunscreens in the protection against UVR overexposure. The Cancer Institute particularly notes the addition of X.5 SPF testing and reproducibility of results which should help to ensure that sunscreens provide the claimed level of protection. We particularly support the more stringent methodology of determining the SPF level defined in the revised guidelines over those previously used in AS/NZS 2604:1998.

The Cancer Institute commends the TGA for including the more detailed section X.4 Labelling of therapeutic sunscreens. This section should improve labelling of TGA regulated sunscreen products by more explicitly outlining how information is presented on the product packaging which should improve the consumers' understanding of the product and how to use it effectively. However, the Institute notes that the labelling section could be strengthened in the following ways:

- Require primary and secondary therapeutic sunscreens include instructions regarding the reapplication of sunscreens. It is recommended this requirement include an upper limit of two hours to reflect current public health recommendations. In relation to this, claims of water resistance with upper limits of four hours may lead to confusion since public health recommendations encourage reapplication every two hours.
- Require both primary and secondary therapeutic sunscreens to include warning statements regarding the effect of prolonged exposure to the sun and the importance of other means of sun protection. Consumer may rely more on a product's SPF level rather differentiate between a product being a primary or secondary sunscreen. Thus, labelling should be consistent across both types.

We have also consulted some clinical experts who regularly advise the Institute's melanoma awareness and skin cancer prevention program. They questioned the scientific basis for allowing SUNSC5 A broad spectrum suncreening preparation of SPF4 or greater (page 9) to bear the claim that it can aid in preventing premature skin ageing. The Cancer Institute NSW recommends the TGA conduct a series of targeted consultations with key experts in melanoma and skin cancers and dermatology, particularly regarding the claim SUNSC5. Advice we have received is that such a claim should only be allowed for broad spectrum suncreening preparation of SPF30+.

[REDACTED]

[REDACTED]

The Cancer Institute NSW thanks the TGA for the opportunity to comment on the Guidelines and hopes that they help improve the effectiveness of sunscreen products in the protection against UVR exposure.

Yours sincerely



Chief Cancer Officer and CEO, Cancer Institute NSW

¹ Cancer Council Australia and Australian Cancer Network: Basal cell carcinoma, squamous cell carcinoma (and related lesions) - a guide to clinical management in Australia. Sydney, 2008

² Tracey E, Ling L, Baker D, Dobrovic A, Bishop J. Cancer in New South Wales: Incidence and Mortality 2007. Sydney: Cancer Institute NSW, December 2009.

