

has correspondence  
3/5/15

April 2005

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

3/5/15

Mr Slater

Dear Mr Slater

**AUSTRALIAN REVIEW OF POLICY FRAMEWORK FOR REGULATING PRODUCTS AT THE COSMETIC/THERAPEUTIC INTERFACE SPECIFICALLY SUNSCREEN PRODUCTS**

I strongly oppose the suggestion to deregulate secondary sunscreens such as moisturisers with a Sun Protections Factor (SPF) of no more than 20.

Sun protection is vital and products with an SPF on the label are seen as providing an important therapeutic benefit.

The mention of the SPF on the label is itself a claim for efficacy of the product, for prevention of sunburn and skin cancer. The SPF is obtained by measurement at a specified application rate (usually 2mg/cm<sup>2</sup>). It is important that label instructions advise how to apply the product to achieve the SPF.

The SPF is also dependent on quality manufacturing methods, stability of the formulation and use before a proven expiry date. It is important that the TGA maintain control over those aspects.

The TGA should require all sunscreen products to be listed on the Australian Register of Therapeutic Goods to ensure compliance with appropriate test method, quality standards, stability tests, labelling, Good Manufacturing Practice and the Australian Standard.

I believe that consumers, their pharmacists and medical professionals need the confidence that this system provides. Anything less is a compromise of public health.

I would be most concerned if, in the country with the highest incidence of skin cancer in the world, any product that makes any claim for sun protection or SPF could be sold as a cosmetic without this level of control by the TGA.

Yours sincerely,

*[Handwritten signature]*



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