THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

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National Manager
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Dear Mr Slater

REVIEW OF THE REGULATION OF PRODUCTS AT THE INTERFACE BETWEEN COSMETICS AND THERAPEUTIC GOODS: SPECIFICALLY SUNSCREENS, DRAFT FOR COMMENT, MARCH 2005

On behalf of the Australasian College of Dermatologists, I would like to set out our views on this issue.

This document contains, under point 4.3, proposals relating to sunscreen products. The Australasian College of Dermatologists (ACD) has a particular interest in this problem because of the high incidence of skin cancer in Australia, the major role of dermatologists in treating it, and the importance of sunscreens as part of any preventative regime. The ACD wishes to make the following submission.

Overview of the ACD's Position

Current research shows that ultraviolet B (UVB) is the major cause of skin cancer and photo-aging. The role of UVA and longer solar wave lengths is less clear cut and the degree to which these wave lengths are involved in the various stages of skin cancer and photo-aging is still being established, as is the effectiveness, and the measurement of the effectiveness, of measures taken to prevent it.

UVB protection is best measured by the sun protection factor (SPF) and the ACD believes that the AS/NZS standard is currently the best and safest way of determining this, despite the limitations of transferring a laboratory-based measurement to the field environment.

The general public, through extensive advertising campaigns, is well aware of the significance of SPF ratings and would recognise the difference between an SPF2 and an SPF20 sunscreen.

Essentially, the ACD believes that the presence of a chemical that has sun screening potential in a moisturiser is meaningless unless it is assessed like any other sunscreen. That means using the current SPF standards. The use of "sunscreen" in a moisturiser, referred to as a "secondary sunscreen" by the AS/NZS standard is frequently misinterpreted by the public (with or without any accompanying claims on

the label), because the word "sunscreen" implies sun protection, and information mentioned later in the document under "concern about a regulatory vacuum" indeed confirms the way in which unregulated use of the word "sunscreen" may be manipulated by cosmetic manufacturers and their advertising consultants. We would, in fact, favour the FDA/US approach of considering moisturisers that contain sunscreens as drugs as well as cosmetics (page 56) if **any** reference to the presence of a sunscreen is made.

Comment on Pages 56-67 of the Draft
With regard to sunscreens of **Group 1 and 2**, we would agree that they should be left unchanged.

With regard to **Group 3** sunscreens, we agree that with a SPF less than 4, given the likelihood that these are not going to offer significant protection when used in normal field conditions, that they should not be classified as therapeutic products. However, a SPF should be quoted if any mention is made of a sunscreen as being one of the ingredients. Otherwise this may create an alternative pathway for Group 4 sunscreens.

With regard to **Group 4** preparations containing a sun screening substance, there should be no distinction made as to whether this is a primary or secondary purpose, so far as there is a requirement to prove efficacy of the sunscreen. That is, an SPF should be required. Much of the problem of moisturisers with sun screening components arise in this area. It is not appropriate to claim that an active ingredient is a sunscreen within any product without proof that sun screening efficacy can be demonstrated within that product, i.e. a SPF is provided.

Page 58, Discussion of Primary Sunscreen
The College believes that the AS/NZS standard is still the most appropriate standard and that any change to this, particularly following representations related to UK/EU standards, will need to be carefully evaluated with consideration regarding Australian conditions.

Page 59 Group 4 Moisturisers with Sunscreen
Patient experience does not accord with the CTFAA's summary of the Australian position of moisturisers of sunscreen as stated at the bottom of page 60.

Experience suggests that there will be a strong temptation for patients to believe that so long as their moisturiser contains a sunscreen, they are getting significant protection, regardless of whether an SPF is contained on the label. Only the presence of an SPF will allow the consumer any idea of the actual effectiveness of the sunscreening ingredients. It is inappropriate that this SPF should be tested any differently to any other product. We would therefore agree with the Cancer Council of Australia's position, set out at the bottom of page 61, that if moisturisers containing secondary sunscreens were treated as cosmetics, there was the possibility (indeed, the likelihood) of a diminution of standards. This is made more important by the fact that moisturisers are most often used on the face, the major site of all forms of solar damage and skin cancer development.

With regard to the New Zealand situation, the ACD would agreed with Med Safe's preferred position that efficacy should therefore form part of any objectives in the regulation of sunscreens, both primary and secondary. Particularly with mention of a sunscreen ingredient, efficacy should be proven. The examples set out on pages 62-64 are not convincing in demonstrating a need for any SPF cut off, below which

regulations should be liberated and they completely reinforce the potential for industry manipulation if the regulations are relaxed.

As stated towards the bottom of page 64 "after examining many such products the report concludes that moisturisers with sunscreens look alike and are cosmetics and behave so in the market place". Therefore, no references should be made to them containing a sunscreen or having sunscreen potential if this is not measured.

Page 65 talks about the problems with imports and the possibility that "peer group pressure" will provide regulation. This is a risk that the ACD does not recommend be taken. The regulations proposed that relate to a cut off volume or weight and the claims regarding water resistance and broad spectrum should be dealt with according to the AS/NZS standard.

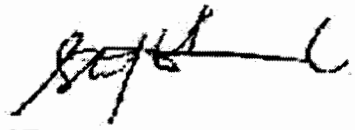
Recommendations
In summary, with regard to the recommendations on page 68, we would agree with 4A.

4B Primary sunscreens - SPF <4 should be treated in the same way as SPF>4, i.e. a toughening of the present standards, as the current proposal for deregulation allows a possible mechanism for abuse of the principle that any sunscreen ingredient claim needs some proof of efficacy.

4C - We would oppose the deregulation of moisturisers that contain sunscreen for a secondary purpose for all the reasons stated above.

The ACD would be happy to answer any questions on the issues raised by us above.

Yours sincerely



STEPHEN SHUMACK
Honorary Secretary