



**Cancer
Society**

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Dear Mr Slater



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**Cancer Society of New Zealand's opinion on TGA
"Review of the Regulation of Products at the Interface between Cosmetics
and Therapeutic Goods" (The Newgreen Report)**

Introduction

The Cancer Society of New Zealand Inc (Cancer Society) is recognised as the leading authority on sun protection and skin cancer prevention in New Zealand. The Society plays an important role in educating and advocating for high standards in the provision of sun protection/skin cancer protection products in this country.

Also, the Cancer Society is a key provider in New Zealand of sun protection/skin protection products, and should have been identified as such and involved early in the review process.

The Cancer Society therefore has a unique ability to comment on this proposed legislation.

Recommendations

We seek removal of Section C of the recommendations on sunscreens in this report, and ask that sunscreens with moisturisers be regulated on the same basis as primary sunscreens, on the basis that:

- All products with an SPF are therapeutic,
- From experience we are aware that a lack of regulation will allow for misuse of the SPF claim
- These changes will be detrimental to the skin cancer prevention message, and to the confidence of the public in sunscreens as a whole.

General Comments

The Cancer Society notes the release of the report on *the Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods* (The Newgreen Report). The report was developed partially as a result of a review of the regulations governing certain products and partly in response to a request by certain parts of the Australian cosmetic industry. If ratified, it will allow moisturisers with sunscreens to be much less regulated than they currently are in Australia. This will have a substantial impact on the New Zealand sunscreen market in the future as Australia and New Zealand work towards a common regulatory agency.

As a concerned and influential stakeholder in the regulation of SPF products we are disappointed that we have not been consulted thus far and we would like to lay out the serious concerns we have regarding the recommendations of the Newgreen Report. In short, we feel that this proposal would represent a large step backwards, and will in no way benefit the public of either Australia or New Zealand. It would also be contrary to the stated aim of the report to 'maintain and enhance the protection of public health, safety and environmental standards.'¹

Skin Cancer in New Zealand

Skin cancer is the most common form of cancer in New Zealand.² Incidence and mortality rates for melanoma in New Zealand are among the highest in the world, with this country having the highest death rate among OECD countries.³ Skin

¹ Newgreen D. (2005) *Review of the regulation of products at the interface between cosmetics and therapeutic goods*. Australian Department of Health and Ageing, Therapeutic Goods Administration. (p V.)

² O'Dea, D. (2000). *The costs of skin cancer to New Zealand*. Wellington School of Medicine, University of Otago.

³ IARC. (2001). *Clobocan 2000: Cancer incidence, mortality and prevalence worldwide, version 1.0*. IARC CancerBase No. 5. Lyon: International Agency for Research on Cancer.

cancer kills around 300 New Zealanders every year, and costs the New Zealand health system over \$33 million per annum.⁴

Most skin cancers are considered to be caused by excess exposure to solar ultraviolet radiation, and, therefore, are potentially readily preventable.^{5 6} A recent WHO report states that the 'encouragement of sun-protective behaviour is the most effective public health measure to reduce the incidence of skin cancer.'⁷ The use of sunscreen with an SPF 30 plus is recommended as a key component of sun protective behaviour.

The Minister of Health has recently launched the New Zealand Cancer Control Strategy: Action Plan 2005 – 2010, a strategy that the Cancer Society has been a key stakeholder in developing. This identifies six goals, the first of which is to 'reduce the incidence of cancer through primary prevention.' One of the objectives for this goal is 'reduce the number of people developing skin cancer due to UV radiation exposure.'⁸

The Cancer Society of New Zealand's goal is to reduce the proportion of New Zealanders who develop and die from cancer.⁹ Specifically, the reduction of skin cancer incidence and mortality is a priority health promotion goal.

We are very concerned that if deregulation continues as suggested by this report, this will have a detrimental impact on the New Zealand population and on our already high (when compared internationally) skin cancer rates.

Background in Sun Protection

The Cancer Society began its first public education campaign about the dangers of over exposure to the sun in 1988. Since that time, the Cancer Society has been at the forefront of promoting SunSmart behaviour, of which the appropriate use of sunscreen is a strong component.¹⁰

⁴ O'Dea, D. (2000) *The costs of skin cancer to New Zealand*. A report to the Cancer Society of New Zealand. Wellington School of Medicine, Wellington.

⁵ International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Solar and Ultraviolet Radiation*. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Vol. 55. 1992, Lyon: International Agency for Research on Cancer.

⁶ Armstrong, B., *How sun exposure causes skin cancer: an epidemiological perspective*, in *Prevention of skin cancer*, D. Hill, E. D.R., and J.M. Elwood, Editors. 2004, Kluwer Academic Publishers: Dordrecht.

⁷ World Health Organization, *World Cancer Report*, ed. B.S. Stewart and P. Kleihues. 2003, Lyon: IARC Press.

⁸ Cancer Control Taskforce. 2005. *The New Zealand Cancer Control Strategy: Action Plan 2005 – 2010*. Ministry of Health. p27-31

⁹ Cancer Society of New Zealand Inc. 2002. *Strategic Plan Review 2002 – 2005*.

¹⁰ Reeder, A.I. (2005). Report to the Skin Cancer Steering Committee to inform development of the Skin Cancer Control Programme Plan 2005.

In the early 1990's, the Cancer Society became aware that there were no regulations governing sunscreen in New Zealand. Around that time the Ministry of Health also released research which created controversy and consumer confusion in New Zealand regarding the quality of sunscreens on the market.¹¹

Recognising the need for a sunscreen to be available that was both good quality and had credibility with the public, the Cancer Society launched its first range of sunscreen in 1992. The public response to this was very positive, and the Society has watched its market share grow from year to year. During 1997 it became the Number One selling sunscreen in New Zealand, a position it continues to maintain today¹².

The Cancer Society therefore has a unique ability to comment on this proposed legislation as the organisation funded by the New Zealand public to help reduce the risk of developing cutaneous malignant melanoma and non-melanoma skin cancers (NMSC), and as an organisation with a strong knowledge of the sunscreen industry and with significant influence based on the level of current and ongoing public and political support in NZ.

Sun Protection Factor (SPF)

The words Sun Protection Factor (SPF) in our opinion constitute a therapeutic claim and are not just the name of a testing standard. While the report puts forward the argument that SPF does not promise any therapeutic benefit, item 6.2 of the Australian/NZ Standard for sunscreen products (AS/NZ2604:1998) clearly identifies that therapeutic benefit or protective factor can be categorised on a product relative to its SPF factor. Further there is a clear expectation by the consumer that a certain level of SPF denotes an expectation of a certain degree of sun protection. Whether or not the information on the pack can be classified as a strict therapeutic claim, the consumer will buy a product on the basis of its stated SPF, expecting a therapeutic benefit.

The actions of sunscreens clearly have therapeutic benefit, both by preventing the painful and unwanted effects of sun burn, and also by helping prevent the long term effects of excessive exposure to Ultra-violet Radiation (UVR). There is a clear association between excessive exposure to UVR and skin cancer and by claiming benefits against UVR, there is a link with skin cancer even if it is not stated. The SPF number determines the level of protection a product offers. It is the SPF protection that reduces the absorption by the skin of UVR, in particular UVB radiation. Excess exposure to UVR can lead to the development of skin

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¹¹ *Consumer* magazine (1993) 'The Half Baked Sunscreen Debate' 322:6-9

¹² AC Nielson Scantrack Data (2005) Total Sunning Preps

cancer. Lifetime cumulative exposure to UVR is linked to the onset of NMSC whereas two to three incidences of severe sunburn before the age of 20 is linked to the onset of melanoma. Therefore a product that helps reduce exposure to UVR can help prevent a disease.¹³

Furthermore, the use of SPF as a rating system for sunscreens has been a consistent and key component of the Cancer Society health promotion messages. Our message has always been that it is important to use sunscreen as part of an over all strategy to prevent UVR exposure (Slip, Slop, Slap and Wrap) and that higher SPF rated products should be used as they will offer more protection.

The type of product that bears an SPF claim does not matter. The public are entitled to be assured that they can have confidence in the concept of an SPF regardless of what product they are purchasing. We note in the Newgreen Report that the Food and Drug administration in America share a similar view.¹⁴

The terms "primary" and "secondary" sunscreen are neither known nor understood by the public. We would suggest that consumers understand only the benefits of what SPF means and that there is a belief that products which have an SPF rating offer protection from the sun. Furthermore, the differences between what is a primary and a secondary sunscreen are not always clear-cut.

In contrast to the assertions of the Cosmetic, Toiletry and Fragrance Association of Australia (CTFAA), we would argue that UV protection is an important factor in many purchasing decisions for moisturisers¹⁵. The observation that moisturisers with SPF have increased their market share at the expense of those without SPF, would suggest that having an SPF rating is of importance to at least some consumers, as is the placement of SPF claims in prominent positions on the packaging of some moisturisers with sunscreens.

Consumers therefore have a right to be assured that the product that they have purchased is what they have been led to believe it is, whether it is described as moisturiser or sunscreen. A consumer is likely to realise that a 50ml glass jar of moisturiser with SPF costing \$50 - \$100 may not be the product to choose for a day at the beach with the children. However, this does not diminish the consumer confidence/trust placed on the product's SPF rating.

¹³ Hill D, Elwood J.M and English D. (2004) Prevention of Skin Cancer p55, p141, p319-322.

¹⁴ Newgreen D. (2005) Review of the regulation of products at the interface between cosmetics and therapeutic goods. Australian Department of Health and Ageing, Therapeutic Goods Administration. (p.56)

¹⁵ Newgreen D. (2005) Review of the regulation of products at the interface between cosmetics and therapeutic goods. Australian Department of Health and Ageing, Therapeutic Goods Administration. (p60.)

The Need for Regulation

Citing New Zealand's current SPF product market as a good role model for shaping future regulations is inappropriate. It has long been recognised that the regulations surrounding sunscreens in New Zealand are poor, and the introduction of tougher standards pending the completion of work to harmonise regulations by the Joint Trans-Tasman Therapeutic Goods Agency is required.

Industry self monitoring, from our experience is not effective. Untrue or deceptive claims continue to be made, and these issues are difficult and expensive to resolve. In the past we have been forced to embark on prosecutions under the Fair Trading Act, against the making of false claims, and products which make claims that could be deemed to be misleading remain on the market. We have found that challenging these sorts of statements requires a substantial commitment of time and resources, as well as perseverance to register and monitor claims about products, without any guarantee of a satisfactory result. Simply stating that a few poor performers have at one time or other been withdrawn or reformulated¹⁶ belies the efforts and costs that organisations such as the Cancer Society have to put into such cases.

The Cancer Society is a charity that receives no direct Government funding for its operation. It is not an enforcement agency, and we would prefer to be able to leave the monitoring of sunscreen regulations to others. Our products have provided a benchmark for sun protection in New Zealand through our continued adherence to the New Zealand and Australian standard. However while the market remains unregulated there is no guarantee that all other products will perform and meet a necessary level of standard.

Changes to the regulations as recommended by the Newgreen Report

The proposal in the Newgreen report that moisturisers containing an SPF ≥ 4 and ≤ 20 should no longer be classified as therapeutic products is contrary to the very aims of the report which are to "maintain and enhance the protection of public health, safety and environmental standards." We would therefore like to suggest that the whole of Section C of the recommendations on sunscreens be removed. Specific areas of concern are as follows:

We question why SPF 20 has been chosen as the cut off for what constitutes a secondary sunscreen. We suggest that this is based on what the author of the report found available in the market during his survey of Wellington supermarkets, and believe that this is an important issue that requires further investigation.

¹⁶ Newgreen D. Review of the regulation of products at the interface between cosmetics and therapeutic goods. Australian Department of Health and Ageing, Therapeutic Goods Administration. 2005. (p62, p65.)

The majority of primary sunscreens available are in the range of 15 – 30+. By allowing overlap, there is the possibility of confusion.

However, given our stance that an SPF claim effectively constitutes a therapeutic claim we don't believe any one organisation should or could determine an arbitrary cut-off number given the wide range of SPF numbers claimed in the market. We believe this matter should best be determined by a wide range of industry groups such as those represented on the Sunscreen Standards Committee – CS42 as it falls within the scope of AS/NZS2604. If the timeframe for the implementation of this report does not allow such consultation, then it would be best to remain with the status quo.

We do not agree with the overall direction of the recommendations of this report in relation to secondary sunscreens, as we find the way that this report has defined moisturisers in association with sunscreens is overly complicated and neither intuitive nor easy for consumers to understand.

There is nothing concrete available in the suggested regulations that would allow a consumer to easily pick out a primary sunscreen from a moisturiser with sunscreen. It is feasible that two almost identical products could be created, one which complies with primary sunscreen regulations and one which does not; the only way to tell them apart would be the presence or lack of a few items of small print.

Even looking at what is currently available we believe that there is little to distinguish the products. The table given on p61 of the Newgreen Report appears to try to distinguish the two types of products. However we would suggest that rather than there being a few exceptions, there is a large variation in what is available in the marketplace. Furthermore, as much of which is available breaks several of the 'rules' stated, this is a flawed method of regulating products. For example the primary claims and pack labels of many moisturisers include statements that refer to UV, and or SPF such as 'Olay Complete UV defence moisture lotion' or 'Neutrogena Moisture SPF15 combines long lasting moisturisation with effective sun protection.' Though many don't mention skin cancer, neither do many primary sunscreens. The claim that sunscreens are slightly greasy and have high viscosity would not account for the great variety of products available on the market in formats such as sprays and gels, and the improvements in sunscreen formulations over recent years.

Aspects such as price, pack size and the way products are displayed in stores are nothing but current fashion in marketing and branding. Just looking at our own Cancer Society range of products, there is a range of pack sizes from 50ml through to 2.5litres, not just 'large plastic packs', as per the table. It is not practical to try to separate products on the basis of these sorts of attributes.

The idea of building regulations to suit the goods available in the market is flawed. Defining sunscreens on the basis of the way the product is packaged and advertised, as seems to be the case in the Newgreen Report, will ensure that it will be easy to sidestep regulations and bring products to market that appear to be a primary sunscreen while not adhering to the regulations for these products.

Summary

It is the position of the Cancer Society of New Zealand that a rethink of these proposed changes is required, and that the status quo should remain. These changes will have many implications for both Australia and New Zealand and on this basis we believe that the consultation held to date has not included all of the relevant stakeholders.

The preference of the Cancer Society is for any attempt to deregulate moisturisers with sunscreens be abandoned. We believe that all products that refer to an SPF rating are making a therapeutic claim, and by allowing some to be less regulated could lead to confusion and misuse of the SPF claim.

We believe that any attempt to do this will lead to a diminution in both standards and the public perception of sunscreens, which would be detrimental to the health messages that organisations such as ourselves work hard to promote and is contrary to the stated principle of this report 'to maintain and enhance the protection of public health, safety and environmental standards.'

Thank you for considering the concerns we have raised in this submission.

Yours Sincerely



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cc Susan Martindale, Medsafe
Craig Sinclair, Australian Cancer Council