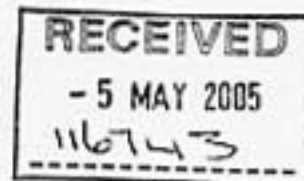




Ross Cosmetics Aust. Pty. Ltd.



PWC/mm

4 May 2005

Mr Pio Cesarin
Director Non Prescription Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Mr Cesarin,

**Re: "Review of the Regulation of Products at the interface between cosmetics and therapeutic goods"
Recommendation 4 C.**

Ross Cosmetics is the largest manufacturer and supplier for sunscreens in the Australian Market. We currently produce about 35% of the total sunscreen sold in Australia on a volume basis. We have a long history of involvement in this industry, and have provided significant inputs in the past in the area of Standards development and Regulatory Change. We also work closely with other manufacturers in the market to ensure our voice is not drowned out by special interest groups such as CTFA and Accord. In this matter our opinions are shared by Ensign Laboratories (contact Mr P Thornborrow Managing Director), a manufacturer with similar market share and history of involvement in the Industry.

Ross Cosmetics is in disagreement with Recommendation 4 C. of Mr Newgreen's report. We believe the adoption of this recommendation, the classification of moisturisers with an SPF of up to 20 as cosmetics, would blatantly contradict the first Guiding Principle for reform "The primary consideration will be to maintain and enhance the protection of public health, safety and environmental standards, consistent with (the various applicable Acts)"

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1. The "Grey Area". Some History

Much emphasis is given in the report to this matter, and the need for clarification, but what is the reality? In the Australian market there has been a clear distinction for many years between what was considered to be a Therapeutic Listable product, and what was not. The disallowance of moisturiser as a primary purpose claim, while a source of annoyance for importers of finished product, has allowed for a common sense offering to be presented to our consumers.

Before consideration is given to reversing the previous position, we suggest some consideration be given to the reasoning behind it. When Sunscreen products were originally regulated in Australia there were a number of Manufacturers operating at various levels outside the control of TGA. There was a perception that some of these Companies may attempt to continue to manufacture Sunscreen products under the guise of Cosmetics, and thus avoid the need for Registration or Licensing. Where there was a clear primary purpose for the product that was separate to its' Sunscreen Claim it was agreed this did not pose a serious risk. Examples of such products are Lipsticks and Foundation. However there was a concern that Moisturisers could be presented to the market that the Consumer could mistakenly believe were Primary Sunscreens. Since this decision was taken there has been a significant amount of education of Consumers towards the understanding that such products are Therapeutic. Thus the position adopted many years ago has been reinforced in the market, and is more applicable now.

The method of manipulation of the appearance of the product will be addressed later in this submission, but it is our contention that the recommendation fails at the first hurdle. That is, if the provision in relation to Moisturisers was originally included in the interest of Public Health, and if the only possible change in the intervening period has been enhancement of this position, then removing the provision is clearly not consistent with guideline 1.

2. What is a Moisturiser.

Contrary to positions that seem to be held by various lobbyists, it is obvious that moisturiser, moisturising etc. are generic terms. A simple examination of a range of products manufactured by this company reveal the use of this term is widespread across products ranging from lipsticks, night creams, day creams and even SPF30+ Primary Sunscreens. A short walk through any retailer confirms that such moisturising claims are present on a high percentage of cosmetic products other than simple creams and lotions. (Our brief survey identified the claim on about 60% of decorative lip products. The claim was used extensively across the spectrum, even in the Hair Care market) The consumer simply expects this property to be inbuilt into any formulation.

In the market today it is not simply enough to claim "moisturiser" as a product description. Any new product needs something else to sell itself. This can be through exciting sounding new actives (maybe new names for the same old things), anti-aging claims, wrinkle reduction etc. SPF claims on such products are being actively sought by various lobbyists because they believe the Consumer is educated to think they deliver on a promise, and can thus be exploited. The down side of this is the resultant undermining of trust in the same therapeutic claim in the case of Primary Sunscreens.

3. What makes a Sunscreen Therapeutic?

The assertion in the report that an SPF, of itself, does not constitute a Therapeutic Claim is baffling.

Attachment A is an example of an SPF30 Primary Sunscreen and an SPF15 Primary Sunscreen currently produced by this company for the Australian market. [REDACTED]

[REDACTED] While at a first glance it is clear that these products are intended to be recognised by the Consumer as Primary sunscreens, the main characteristic identifying this is the SPF claim. Both products make no use of the word "sunscreen", and the only other claim is the small print reference to water resistance. Clearly in this case the SPF claim is used to identify the product to the consumer as a Primary Sunscreen.

Attachment B is a depiction of the same Primary Sunscreen products with an additional SPF20 moisturiser. It is our contention that this SPF20 product would be considered, if the Newgreen recommendations were to be adopted, to be a cosmetic product. The contents of the bottle could be made to look and smell like a sunscreen.

The consumer would have great difficulty distinguishing between these products. There is a significant risk that a given consumer will purchase the cosmetic lotion with an expectation of a therapeutic benefit. The report makes the point that there is an "...absence of basic sanitary controls on cosmetic manufacturing premises in Australia..." If there is a significant risk that a consumer will have an expectation of a therapeutic benefit of a product that has been produced in unknown conditions, possibly without Quality Assurance testing or even the most basic microbiological testing, then guideline 1 is not met.

The SPF study is a laboratory test. However it is a laboratory test with a biological endpoint that is used, in the absence of a better method, to determine the therapeutic benefit of a sunscreen. To dilute the importance of this measure by relegating its use to cosmetic claim clearly risks reducing the perception of benefit the consumer will attach to SPF30 Primary Sunscreens.

Again, to risk undermining the Consumer's confidence in the SPF study as a means of identifying a Therapeutic product is clearly at odds with guideline 1.

Further extending this point, the adoption of SPF20 as the maximum claim for the proposed non-therapeutic moisturising lotion simply because it is the maximum that was "seen in New Zealand" is commercially driven nonsense. The report actually admits that the reason for this limit is not underpinned by a scientific argument, or an established cut-off recognised by consumers. It is because of "... formulation complications that detract from the cosmetic nature of the product..." The logical conclusion to draw to this point is that if a product can be formulated that does have a "cosmetic nature" and achieves SPF30 it should be considered a cosmetic and not a Therapeutic. It is clear that the SPF20 limit has been arrived at as a level of convenience for various interested parties within lobby groups, and has no basis in public health.

It is of further concern that the SPF20 limit may be being used as a stepping stone towards the preferred position by some groups, which is total deregulation of sunscreens. It would seem a simple extension of the Newgreen position to, at some future time, claim that SPF30 is not a therapeutic claim because TGA have already said SPF20 is not.

4. Difference in application of moisturisers and sunscreens.

The Australian New Zealand Standard ANZS2604-1998 specifies a dosage of 2 mg/sq.cm be applied to the skin for the purpose of SPF determination. Much effort has been put into educating the consumer about the need for generous application of product. Some of our clients actually specify amounts to apply. For example one recommends half a teaspoon per arm. On the other hand moisturisers are designed to "rub in to the skin". This is actually a misnomer, as the product is designed to dry down and spread on the skin with the impression of disappearing.

A review of customer complaints relating to sunscreen products over the last two years at this company revealed that, with the exception of a few skin reactions, all were confirmed to be, or most likely to be, attributable to insufficient product being applied prior to sun exposure (36 cases). In house studies have shown that a moisturiser is applied at a far reduced rate to that specified in the standard. The actual number is formulation dependant, and also influenced heavily by other factors, but about 50-70% film reduction is likely. Thus if a consumer applies a moisturiser at usual cosmetic levels, an SPF20 labelled product may only provide protection of less than half the expected level. Again this is clearly not in the interest of public health.

5. Market Implications- Health Ramifications

With our extensive experience in Product Development and Marketing in the Australian and New Zealand markets Ross Cosmetics is in a good position to predict the outcome of adoption of the Newgreen recommendations. Firstly, we estimate that an SPF20 moisturiser will be able to be formulated for approximately 60% of the cost of an SPF30 Primary Sunscreen. Cost savings would be gained in removal of the water resistance requirement, and in the slight reduction in active ingredients. The SPF20 product as depicted in Attachment 2 will provide the ideal low cost entry product into the sunscreen market. It will look like a sunscreen and be much cheaper. If reputable companies refuse to make the product this doesn't matter because, with the absence of requirements for GMP, it can be made anywhere. This is clearly at odds again with guideline 1.

Conclusion

The attempt by Newgreen to clear up the interface between Cosmetic and Therapeutic products simply moves the grey area closer to the Therapeutic end of the scale. It therefore puts at risk significant education of our consumers into the benefits of Sunscreen use, confuses the market, risks the introduction of substandard products with therapeutic claims and is thus at odds with its own guidelines. We strongly suggest the current position be retained in the interest of public health.

Yours faithfully
ROSS COSMETICS AUST PTY LTD



PAUL CASTLES B.Sc.
TECHNICAL DIRECTOR

Att.

Attachments A and B have
been removed at the request of
Ross Cosmetics Aust Pty Ltd