Ego Pharmaceuticals Pty Ltd

Australia's Dermatological Specialists

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

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National Manager
TGA

By Express Post and Fax to 02 6232 8239

Dear Mr Slater

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

Ego Pharmaceuticals strongly opposes the draft proposal (the "Proposal") to deregulate secondary sunscreens with an SPF of no more than 20.
Ego believes that all sunscreens – that is all products that make *a quantified* sunscreening claim including mention of SPF – should be regulated in an identical manner by TGA.

This is consistent with the guidelines for reform of the regulation of products at the cosmetic-therapeutic interface. The primary consideration must be to maintain and enhance the protection of public health and safety consistent with the lowest level of regulation. No less regulation than is currently imposed will guarantee sunscreen products will deliver the protection they claim.

No monitor of cosmetics would mean no monitor of secondary sunscreens

I am a former member of the Committee responsible for the Australian Standard/New Zealand Standard 2604 on sunscreen testing and labelling (the "Standard"). I was a member of the Committee that was responsible for arguing for the increase of the label SPF from SPF 15+ to SPF 30+. This process took some 5 years to get this modest change for the improvement of public health. Since this introduction consumers have had access to products that are twice as protective, contain no more absorbing sunscreen actives and are no more expensive than the former SPF 15 products.

The Proposal to de-regulate sunscreens with SPF no higher than 20 would undermine all the work that was done. It would **make the Standard almost redundant as there would be no one in practice to enforce the Standard**.

I am also a Past President of the International Federation of Societies of Cosmetic Scientists (the international umbrella group of professional scientific societies representing 14,000 scientists in 40 countries).

For the cosmetics industry there is **no industry complaints procedure at all.**
In Australia and indeed in New Zealand there is **no effective monitor of the cosmetic market**, of claims made, of products, of quality.

21-31 Malcolm Road, Braeside, Victoria 3195 Australia
Telephone (03) 9587 1088 International +613 9587 1088 Fax (03) 9580 7647 www.egopharm.com ask@egopharm.com
ABN 86 005 142 361

Primary sunscreens will not be able to compete with secondary sunscreens.
It will be very hard for primary sunscreens to compete with deregulated secondary sunscreens. This will ultimately mean that much, if not all, of the sunscreen market will move to secondary sunscreens. Who for instance will be there to monitor if the secondary sunscreen claim is more prominent than the primary cosmetic claim? A secondary sunscreen will have both cost and marketing advantages.

Cost advantages of secondary sunscreen over primary sunscreen:

- No requirement to use compendial ingredients.
- No listing of ingredients on the ARTG, so no delay and faster to market means competitive advantage, no additional Australian specific testing, no fees.
- No TGA product fees or audit fees.
- No time spent in preparing for and responding to TGA or any other audits or in improving quality systems.
- No control over what is claimed as a sunscreen, listing sunscreens actives as excipients or vice versa if this suits the manufacturer
- No effective monitor of SPF testing [Why test every formula? They have the same actives after all and we only changed the fragrance and one other excipient. Why test to the method of AS 2604 which is close enough to method XYZ.].
- No need for stability data. This reduces cost and time to market giving significant competitive advantages. How would we know if the product is what is on the label? **Degradation of an unstable product will affect the SPF.**
- No need for expiry date on label. The proposal suggests the expiry date is not needed if the stability is acceptable for 3 years, but there is no guide for cosmetic stability testing and no-one to regulate cosmetics, so in practice no expiry dates validated by audited stability testing would occur.
- No requirement for manufacturing validation. TGA are requiring an increased focus on this area at audit.
- No requirement for microbiological control during manufacture or of the preservative efficacy. Preserving quality sunscreens is a challenge.
- No requirement for manufacture under any code of GMP.

These are all significant costs that can and will be eliminated by manufacturers at the lower end of the market under the Proposal.

Marketing advantages of secondary sunscreen over primary sunscreen:
There is recent (January 2005) market survey evidence that consumers **still believe that they really only need an SPF 15** sunscreen. (There is evidence in the literature that SPF 15 does not provide adequate protection for a period of 4 hours in the sun).
Cosmetics can make claims to consumers of recommendation by healthcare professionals. Products on the ARTG cannot (under the TGAC). Cosmetics can make claims that TGA have disallowed including:

- Contains anti-oxidants
- Contains free radical scavengers

As mentioned above, cosmetics can get to market significantly faster due to the lack of requirement for testing (SPF, stability, preservative and more) and approvals (ARTG, TGA). This allows cosmetics to introduce new ingredients earlier than products on the ARTG and thus they gain a competitive advantage.

Cosmetic directions are not monitored to ensure they reflect the testing conditions, (in fact no testing is monitored). Therefore the cosmetics can advise applying very little very infrequently and thus appearing much more potent that a primary sunscreen. This **would pose a health risk by increasing the amount of UV the skin sees.**

There is recent (June 2004) market survey evidence that consumers believe that all the products they use including cosmetics are overviewed by an appropriate government authority. Cosmetics are not.

Consumers and health professionals certainly have a right - and probably an expectation - to believe that every product making *any* sunscreening claim is regulated by TGA. The quasi-government anti-cancer organisations have been advising the public for decades to take sun protection measures, including using sunscreen. Hence the **public belief that every sunscreen is regulated by the government is reasonable and strong.**

The proposal would cause confusion, misleading consumers to use lower quality products.
I submit that a dermatologist, a pharmacist and the consumer may find it difficult to choose between:

- a product that is a primary sunscreen 'SPF 30+ broad spectrum' that can claim only the coded indication 'may help protect against skin cancer'.

and

- a secondary sunscreen that is 'SPF 20 broad spectrum', 'protects against sun damage', 'contains anti-oxidants to absorb free radicals and thus acts as a secondary defence to protect the underlying layers of the skin' and 'recommended by dermatologists'.

New Zealand experience shows de-regulation is wrong.

In New Zealand sunscreens are treated as unregulated cosmetics, with compliance to the Standard being optional. It has not worked. **Sunscreen products that breach the labelling requirements of the Standard are regular features** in the market there. And of course there is **no control or knowledge of *any* quality processes** used the manufacture of these products – they are unknown entities.

Compliance and Sunscreens - Recent History

To look at compliance and what we can expect for de-regulated sunscreens we only need to look back at the recent history. Listing was introduced around 1997. At this stage sponsors were required to give TGA assurances that they held evidence of SPF testing, stability data and manufacturing according to the code of GMP. Despite this it was well known that **a number of the products on the market did not have this data.** This number was increasing and Ego had been told that Pan Pharmaceuticals was about to enter this market. In this time **there were a number of quality related sunscreen recalls** at least one of which was related to the product purporting itself to be SPF 15 when in fact it was SPF 8.

Pan is an example of what happens if a lowest cost manufacturer is able to operate. Credible manufacturers either get swallowed up (eg. Cenovis bought by Mayne) or join the ranks (eg. Mayne getting Pan to contract manufacture their products). Pan's entry into the sunscreen market would have been diabolical for Ego. Ego is a company with a core value being "Product quality is our way of life". The margins in sunscreens are low, the market is ruthlessly competitive, sales depend on unpredictable weather, and the costs of compliance and of making quality products are high.

This situation changed dramatically when the TGA took action in this matter. There was widespread testing of sunscreens by the TGA followed by Section 31 notices being sent out to non-compliant companies. Slowly the situation improved. Today the sunscreen industry is much closer to a level playing field. Clearly, even having a Listable system is not enough. The regulator has got to be involved. There must be consequences of non-compliance. It would seem to make no sense for the TGA to delegate this responsibility to the ACCC. **Why should Australia have two separate bodies regulating one industry.** Which body regulates the interface? This approach can only take longer and be less effective than the current system. Note that a whole year's sunscreen business occurs in about 3 months, during which time huge competitive damage can be done by a ruthless unregulated company breaching the Standard. **Having two bodies (TGA and ACCC) regulate one sunscreen industry is an increase in regulation, against the COAG principles.**

To implement the Proposal is to open Australia up to low quality secondary sunscreens from 3rd world countries. Interestingly it may be the cosmetic houses from first world countries that are the first to do this. There is no way that Australian pharmaceutical manufacturers will be able to compete. It is no wonder that the larger contract manufacturers (Ross Cosmetics, Ensign Laboratories and Sentel Pacific) are against this change. They have very recently up-graded their facilities to the appropriate GMP standards, now to be told that this will no longer be necessary. **Could there be a more backward step for Australian industry, for Australian public health?**

Conclusion

Sun protection in Australia is vital and certainly products with an SPF or "broad spectrum" on the label are seen as providing an important therapeutic benefit. **We are talking of quantity as well as quality of life in this important therapeutic category.**

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 $2mg/cm^2$). It is important that label instructions advise how to apply the product to achieve the SPF. It is important all the test methods and labelling requirements set out in the Standard are followed.

The SPF is also dependent on quality ingredients, quality manufacturing methods, stability of the formulation, controlled storage temperature, proven preservative efficacy and use before a proven expiry date.

The use of the term SPF without the assurance that it delivers the expected protection undermines the credibility of the measure for all sunscreens.

There must continue to be controls by the TGA over all these aspects, for *every* product that makes *any* sunscreen claim.

The TGA should require all sunscreen products to be listed on the Australian Register of Therapeutic Goods.

The TGA must continue to ensure compliance with appropriate test methods, quality standards, stability testing, Good Manufacturing Practice and the Australian Standard **for this and all other categories of ARTG Listable products.**

We believe that consumers and their pharmacy and medical professionals need the confidence that this system provides. Anything less is a compromise of public health and an undermining of decades of education that sunscreens protect our skin.

We would be most concerned if any product that makes a quantified claim for sun protection or SPF could be sold without this level of control by the TGA.

Ego recommends that the draft proposal to deregulate sunscreens is rejected in favour of the *status quo.*

Yours sincerely,

Alan Oppenheim BSc(Hons) FRACI FAICD
Managing Director