AUSTRALIAN SELF-MEDICATION INDUSTRY

BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

Pio Cesarin
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Therapeutic Goods Administration
PO Box 100
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18 May 2005

Dear Mr Cesarin/Dr Hartley

RE: Review of the regulation of products at the interface between cosmetics and therapeutic goods

The Australian Self-Medication Industry (ASMI) wish to thank both NICNAS and the TGA for the opportunity to comment on the above Review.

ASMI believes there is considerable scope to reform a number of interface categories as part of the Trans-Tasman harmonization activities leading to a Joint Regulatory Agency. ASMI would in particular like to emphasise that where we have felt that the protection of public health and safety forms a significant consideration of any part of proposed regulatory form, that such considerations should be conducted from an evidence-based perspective.

ASMI's submission does contain consumer research that should be regarded as commercial-in-confidence. ASMI members providing such information have expressed a willingness to communicate directly with the TGA and NICNAS to assist in providing any clarification or additional information as may be required.

ASMI look forward to working further with both agencies in any subsequent implementation or scoping work arising from the recommendations. Should you require any additional information please do not hesitate to contact me on 02 9923 9411 or by email at jonathan@asmi.com.au

Yours sincerely

Jonathan Breach
Regulatory Manager – Complementary and OTC Medicines

Cc – Dr Margaret Hartley, Director- NICNAS

ASMI Membership 2005

ASMI Members

updated 29 April 2005

Ordinary Members	*Associate Members*
3M Health Care Pty Ltd	ACNielsen
Allergan Australia Pty Ltd	AZPA International
Aspen Pharmacare	Anthea Steans Consulting Pty Ltd
Australian Pharmaceutical Industries	Clare Martin & Associates
Bayer Healthcare Consumer Care	Clayton Utz
Biological Therapies Pty Ltd	Contract Pharmaceutical Services of Australia Pty Ltd
Boehringer Ingelheim Pty Ltd	Cormack Packaging Pty Ltd
Boots Healthcare Australia Pty Ltd	Crossmark
C B Fleet Co (Australia) Pty Ltd	Curtis Jones & Brown Advertising Pty Ltd
Cardinal Health	DFC Thompson Australia Pty Ltd
Church & Dwight Australia Pty Ltd	Engel, Hellyer & Partners Pty Ltd
Combe International Ltd	Euro RSCG Life
Efamol Australia Pty Ltd	Freehills
Ego Pharmaceuticals Pty Ltd	Grey Healthcare Group
Flordis Pty Ltd	Hahn Healthcare Recruitment Pty Ltd
Galderma Australia	H&T
GlaxoSmithKline Consumer Healthcare	IMS Australia Pty Ltd
H W Woods Pty Ltd	Labmark Pty Ltd
ICN Pharmaceuticals Australasia Pty Ltd	Lipa Pharmaceuticals
Johnson & Johnson Pacific	Medi Kwik Pty Ltd (Remedies)
Living Naturally	Pathway International
Mayne Health Consumer Products	Palin Communications
Mentholatum Australasia Pty Ltd	Oz Pharma Contracting & Consulting
Merck Sharp & Dohme (Aust) Pty Ltd	Regulatory Concepts Pty Ltd
Nestle Australia Ltd	Singleton Ogilvy & Mather
Novartis Consumer Health Australasia Pty Ltd	Sue Akeroyd & Associates
Pfizer Pty Ltd	Technical Consultancy Services Pty Ltd
Procter & Gamble Australia Pty Ltd	Ursa Communications
Reckitt Benckiser	
Roche Products Pty Ltd	
Sanofi-aventis Australia/New Zealand	
Schering-Plough	
Smith & Nephew Pty Ltd	
Stiefel Laboratories Pty Ltd	
Wyeth Pty Ltd	

1. Cosmetics

Cosmetics claims guidelines should be established by the Joint Agency, in consultation with stakeholders and other regulators, to clarify the distinction between cosmetics and therapeutic products. These guidelines should be underpinned by legislation if necessary.

ASMI members supported a Joint Agency Cosmetics Claims Guidelines. Legislative underpinning may only be useful if the document is used to indicate where therapeutic claims start, rather than a legislatively underpinned document defining what is a cosmetic claim.

ASMI recommend an industry-government working party be established, and also recommend consumer involvement in the development.

2. Antiperspirants

Antiperspirant preparations that derive their antiperspirant properties from inorganic salts (or their organic complexes) of aluminium, zinc or zirconium only should not be classified as therapeutic products under the Joint Agency. Antiperspirants other than these should be regulated as Class II medicines.

ASMI support the reclassification of in/organic salts of aluminium, zinc or zirconium outside therapeutic goods legislation as part of the Joint Agency. ASMI do not agree that topical antiperspirant products of other actives should by default be regarded as Class II medicines. Antiperspirant use is a low risk cosmetic application, and if a new active ingredient for antiperspirant use is found from evaluation to be of a comparable risk profile to the aforementioned active ingredients, there should be capacity for the General Manager of the Joint Agency to declare all antiperspirant applications for that ingredient similarly excluded from regulation. At the very least such actives should be considered for acceptability in Class I medicines.

3. Antidandruff preparations

Antidandruff shampoos, hairdressings or lotions should be classified as therapeutic products by the Joint Agency.

If the antidandruff product is not included in any Schedule to the SUSDP,
(a) the product should be exempted from licensing; and
(b) the premises where the product is manufactured should be exempt from licensing.

A number of ASMI members who produce "mass market" believe that such unscheduled products for the treatment of dandruff should be similarly excluded from regulation under the Joint Agency, rather than exempt, so as to be consistent with European markets

One of the issues of contention with the current arrangement appear to be the inconsistency where antidandruff preparations as exempt goods require advertising pre-clearance, whereas other categories of exempt goods do not (i.e. disinfectants).

Other ASMI members who market scheduled products believe that the expectation on efficacy for what they regard as a therapeutic action, regardless of consumer perception of the product,

should ensure unscheduled products are retained under some level of control of the expected Joint Agency regime in order to maintain a level playing field.

4. Sunscreens

A. Primary sunscreens where SPF is ≥ 4 *should be classed as therapeutic products and described as Class I medicines. As a condition of licensing, the SPF of each product must be determined by the method prescribed by AS/NZS 2604:1998 for the particular product. The Joint Agency should consider moving to an acceptable international standard when one becomes available. The Joint Agency Rules should specify that all performance statements and markings on the product label (both mandatory and optional) are expressed in the manner prescribed by AS/NZS 2604:1998 and no other.*

The majority of ASMI membership support the retaining of sunscreens with SPF $\geq$ 4 as a therapeutic product and a Class 1 medicine under the Joint Agency.

B. Primary sunscreen products where the SPF is <4 *should not be classified as therapeutic products.*

The majority of ASMI membership support Primary sunscreen products where the SPF is <4 not be classified as therapeutic products. It was felt however that it was the consumer's right to reliably know if the SPF value was accurate and as such these products should still be expected to comply with the Australian New Zealand Standard.

A point has been expressed by members the way part A and B are expressed suggest that a product of SPF 4 or greater conveys some therapeutic benefit. As such it is irrelevant as to whether the product is Primary or Secondary in presentation as the SPF carries a certain implied sun protection benefit to the consumer.

C. Moisturisers that contain a sunscreen as and for a secondary purpose where the SPF ≥4 *should not be classified as therapeutic products provided:*

(a) they meet the definition of secondary sunscreen product. as defined in AS/NZS 2604:1998; and

(b) Any SPF or equivalent category description is disclosed on the label;

(c) the SPF or equivalent category description disclosed on the label is determined by the method prescribed by AS/NZS 2604:1998 for the precise formulation; and

(d) the SPF as disclosed on the label does not exceed 20; and

(e) the formulation is not water-resistant; and

(f) there is an expiry date or use by date on the label if the product is not stable for at least 36 months; and

(g) no therapeutic claims, including any representation about skin cancer, are made; and

(h) any representation about anti-ageing can be made only if the product is defined as a "broad-spectrum product" within the meaning of AS/NZS 2604:1998; and

(i) the pack size does not exceed 300 mL or 300 g; and

(j) all performance statements and markings (both "mandatory" and "optional") are expressed on the product label in the manner prescribed by AS/NZS 2604:1998 and no other.

An Australia- or New Zealand- specific disclaimer or advisory statement to the effect that the product is only for use as a cosmetic should not be compulsory on moisturizers that are secondary sunscreens.

This issue has been the most contentious amongst ASMI members, and one that has placed the majority of members in a contrary view to the recommendations presented in the Report.

It must be acknowledged that some ASMI members are of the view that cosmetic moisturisers with sunscreens should be regulated as cosmetics, not medicines, with a similar relaxation of requirements on GMP, labeling, advertising with compliance issues to be managed under the jurisdiction of the ACCC. This will provide them principally with an easing of market importation of such products from Europe.

The majority view of submissions received by ASMI from membership however were opposed to the recommendation, and their concerns are outlined as follows:

Sunscreens are a continuum, not silos.

Currently both Primary sunscreens and moisturiser with sunscreens may make SPF protection claims up to 30+, and as such carry an implication with consumers as to the degree of protection such a product affords.

In the Report, the position of the Cosmetic Toiletries and Fragrances Association of Australia (CTFAA) is cited as such:

"The CTFAA's summary of the position in Australia is:consumers understand that moisturisers with SPF provide a valuable additional benefit to help protect against intermittent sun exposure and damage but know they are not a substitute for a sunscreen."

It is arguable that the CTFAA position is not consistent with the actual market behaviour of many cosmetic companies. The Australian market is now stocked with products that in addition to moisturising claims, claim sun protection in terms on par with Primary sunscreens. Examples of such products are provided in **attachment 1**.

Of additional concern is a growing trend by some manufacturers of "cosmetic" sunscreen products to start implying therapeutic claims already deemed inappropriate for Listed sunscreen products by the TGA, such as antioxidant action or protection from immunosuppression **(attachment 2)**.

The question is therefore whether a "Secondary Sunscreen" is by definition equated with a product that is not intended to be used for protection from the serious effects of solar exposure.

The definitions are clear

The report further cites:

"This Report submits that Australia should not apologise for the stand that it has taken because of the short and long-term health problems arising from the country's climate, demographics and beach culture outlined at the beginning of this chapter. Accordingly, there should be no change to existing controls on primary sunscreens, with the exception of providing, in the future, for compliance with alternative prescribed standards in determining the sun protection factor and other performance standards when published."

The Report's stand on this point is commendable. However the Report then suggests an interpretation on what constitutes a Primary Sunscreen and what constitutes a Secondary Sunscreen, based on the distortion of the terminology by the cosmetics industry.

Nowhere in the Australia New Zealand Standard (AS/NZS 2604: 1998) is it specified that the sun protection benefits of Secondary Sunscreens is inherently less important than its primary (or co-primary) purpose.

"Primary Sunscreens" have a primary purpose of protecting the skin from certain harmful effects of the sun's rays. A "Secondary Sunscreen" can also be intended for this purpose in a manner **co-primary** to additional functional benefits:

"Section 5.10 Secondary Sunscreen product: a sunscreen product which is represented on the label as protecting the skin from certain harmful effects of the sun's rays while fulfilling another primary purpose (AS/NZ 2604:1998)"

"while fulfilling another primary purpose" can be taken to mean the sunscreening effect is as important as the additional functional benefit.

Under this definition, a combination Insect Repellent-Broad Spectrum Sunscreen is also a Secondary Sunscreen. There would be no justification that the sunscreening purpose is somehow less important than the insect repellent purpose. Why then must it be assumed then that a moisturiser with a sunscreen is by definition "less serious" than a primary sunscreen without additional functional purpose?

From a formulation, and hence safety point of view, there is no distinction between a primary and secondary sunscreen. The SPF measured in the test is a function of the dehydrated film formed on the skin surface, not the amount of actives. Thus, it is possible to have an SPF 15 and SPF 30 product with the same quantity of active. Recommendation (d) defines a category cut-off of "the SPF as disclosed does not exceed 20...". This could be interpreted to mean that a secondary sunscreen could still have an actual SPF of 30 +, but simply be labelled as SPF 20. Up until the 1997 version of the Standard, SPF 15 was the maximum permitted for labelling of sunscreens in Australia, being defined as "Maximum Protection". Secondary Sunscreens with an SPF between 15 and 20 are now "High Protection Sunscreens" within the Standard. It would seem to be inconsistent this group of products could be considered only to be secondary sunscreens.

Regardless of the typical patterns of reapplication, current guidelines recommend reapplication over the course of the day. Moisturisers are often applied only at infrequent intervals, so the efficacy over time after only a single application would need to be considered if a higher SPF (15 to 20) is to be claimed. Indeed it could be questioned whether current directions for use on many moisturiser-sunscreens are sufficient in order to justify the SPF ratings claimed, and whether there is a current issue with misleading labelling that is being largely overlooked.

Recommendation (f) requires expiry dating for product that are not stable for at least 36 months. It has been suggested that sponsors of sunscreens would have little evidence to support their product SPF performance of products aged for greater than three years and that expiry dating should be mandatory in any case. The current requirement under Guidelines for Stability Testing of Sunscreens allows for 9 months at $+10^{o}C$ to be extrapolated to 3 years, but only allows for two-fold extrapolation beyond 3 years. It is unclear how this would be regulated if products were to fall outside the present regime?

The Consumers View

The other assumption used in the Report is that the consumer buying a moisturiser with a sunscreen is a woman, and such buying behaviours by women create a distinction between Primary and Secondary Sunscreens. In terms of marketing to the 'metrosexual' male market, the proposal of a relaxed regulatory regime with a foundation in gender bias is erroneous and ignores the full protection factors that may be sought by men for similar products.

Such consumers may not only have different buying motivations for such products, but also may not use the products in the same way (see **attachment 3**, one of which is used after facial shaving, arguably a usage pattern not typical for most female consumers).

In an article in The Age "Rise of the Metrosexual" (11 March 2003) cosmetics brands such as Ella Bache acknowledge that men make up as much as 40 per cent of their salon customers in some areas.

Thus it is not clear from the 1996 consumer research conducted by CTFAA and ACSPA cited in the Report that the role of gender has been taken into consideration. Nor is it clear what was actually presented to consumers for the purposes of research and whether they were presented with existing products on the Australian market that deliberately blur the boundaries between therapeutic sunscreen and cosmetic. As such their results must be seriously questioned as to the integrity of the reported usage patterns and rankings of importance for SPF, especially across gender.

The CTFAA and ACSPA have identified a number of points that assist in differentiating between moisturisers with a sunscreen and Primary sunscreens. A number of ASMI members disagreed with the identified points as highlighted below:

Attributes	Moisturisers with sunscreens	Primary sunscreens	Comments
Delineators			
1. Product descriptor	Moisturiser	Sunscreen	There is the potential that an SPF claim could mislead a consumer into believing that a moisturiser with sunscreen's primary purpose is to protect from UV rays. How will the SPF factor be adequately

			distinguished in secondary sunscreen products?
2. Claims/Advertising/ Labels	Primary claim is to "moisturise & protect. Makes skin feel good	Primary claim is to "use when in the sun to protect from sunburn". Referenced to skin cancer if SPF >30	There is a risk that secondary sunscreens may be perceived as providing skin cancer protection especially as SPF 15 claim may be considered "high level of protection" In addition Primary sunscreens are also expected to "moisturiser and protect". Recent sunscreen launches by reputable skincare companies verifying this.
3. Instructions for use	Use daily, morning and night, both indoors and outdoors, in all weather conditions. Apply sparingly	For use when going in the sun. Apply liberally and frequently.	There is a great risk with the instruction to "apply sparingly" as it will not deliver the SPF as labelled. All types of sunscreen should be applied liberally.
4. Packaging design	Mainly indoor use. Packs are "fashion statements". Often in opaque glass jars and usually in volumes ≤ 100mL or g	For outside use often, but not always, in larger plastic packs.	Primary sunscreens make fashion statements, and as discussed previously, the primary sunscreen market is evolving with new innovative ingredients & packaging. One of the conditions state that moisturisers with sunscreens are required to be pack size ≤300mL, how will this be a differentiating factor from Primary sunscreens when a vast proportion of primary sunscreens are marketed in pack sizes of ≤300mL?
5. Ingredients disclosure	Quantified actives and unquantified preservatives	Unquantified disclosure of all ingredients	There is nothing in the current Labelling order preventing full disclosure of ingredients, if a company wished to be seen to be responsible and do so.
6. Water resistance	Not water resistant	May or may not be water resistant	
Lesser differences			
7. In-store display	Mainly department stores, pharmacies and supermarkets	Also stored at corner stores, beach kiosks	This should not be considered a differentiating factor as Primary sunscreen products are sold through dept stores, pharmacies and supermarkets.
8. Store placement	Placed with other cosmetics including moisturisers w/o sunscreens	Separate display for sunscreens	No assurances can be given that moisturisers with sunscreens will not be placed amongst primary sunscreens?
9. Advertising	No therapeutic claims	Designated therapeutic claims	As discussed above, there is the potential for consumers to assume "skin cancer protection" in association with an SPF factor, especially an SPF factor up to 20.
10. Body area	Mainly for usually exposed parts of the body such as face and hands	All over use	This should not be used as a differentiating factor as there are primary sunscreens formulated for specific part of the body i.e. face.
11. Sensory	Vanishing	Slightly greasy feel.	As discussed previously the

properties		High viscosity	primary sunscreens marketing is evolving through new & innovative ingredients to ensure more aesthetically appealing formulations, in order for the products to be "vanishing"
12. Seasonality	All year round. Used during cold weather when skin is dry	Generally during hot weather	In the interest of public health and safety, it should be advocated that primary sunscreens be applied all year round. If in fact this is considered a differentiating factor then the potential risk to consumer health is not adequately recognised.

Arguments presented with regard to purchasing trends for purposes of demonstrating differentiation are also potentially flawed as this implies Primary sunscreen products are principally used at only one time of the year. The risk of sunburn from excess solar exposure is not a phenomenon limited to summer periods in Australia, but exists all year round.

The risk factors for UV exposure for both acute and chronic outcomes includes length of time exposed, intensity of exposure, time of day, cloud cover, season, proximity to the equator, altitude and reflective surfaces. While purchase intent may be highest in summer months, this would not detract from the importance of sun protection during winter months at high altitude locations during ski season, or even during the winter months in Northern Australia closer to the equator during the Dry Season when cloud cover is less prevalent.

UV index data published by the Australian Bureau of Meteorology (http://www.bom.gov.au/products/IDY00512.shtml) clearly show that there is a Moderate (UV index 3 to 5) to Very High (UV index 8 to 10) risk from UV during winter months in many parts of Australia, recommending that sunscreen be applied for all levels above IV Index 3 (Moderate). Thus we should not be encouraging a market where a moisturiser could be perceived as replacing a sunscreen during the winter.

Professor Armstrong, head of the School of Population Health and Health Services Research from the University of Sydney has stated that melanomas were most commonly found in intermittently exposed skin, and the most intensive targeting should be aimed at sun-sensitive people such as indoor workers who spend only 10-20% the time in the sun of an outdoor worker (**attachment 4** http://www.usyd.edu.au/publications/news/021005News/1005_cancer.html).

We feel it relevant at this point to reiterate the cosmetics industry position - *"consumers understand that moisturisers with SPF provide a valuable additional benefit to help protect against intermittent sun exposure and damage but know they are not a substitute for a sunscreen"*

Thus the rationale that secondary sunscreen moisturisers are only for intermittent exposure, and thus not a therapeutic intent, runs contrary to the demonstrated need for quality and efficacious consumer protection during those periods of intermittent exposure when a Primary sunscreen is unlikely to be used.

The cosmetics industry has previously made arguments that deregulation for the purposes of increased access and will have a public health benefit. The argument is however circular, in that if these products are providing public health benefit then they should be regulated like other sunscreens.

ASMI has received from **<edited for confidentiality reasons>** the outcomes of consumer research which indicate a contrary consumer view to that ACSPA/CTFA research cited in the Report.

<**consumer research edited for commercial in confidence reasons**>

<**edited for confidentiality reasons**> have indicated to ASMI that they are willing to provide the details of their testing directly to the TGA if required for further consideration.

SPF is Therapeutic According to AS/NZS 2604

Contrary to the assertions of the report, many ASMI members assert that SPF is a therapeutic claim in its own right. The Foreword of the Australian New Zealand Standard states:

"Sun Protection Factor (SPF) informs consumers of the efficacy of the sunscreen against sunburn…"

While a moisturiser with sunscreen may not be appropriate for protection against cancer, it may be appropriate for protection against some degree of sunburn, which is still a therapeutic application.

If it were true that the SPF value does not inherently carry a therapeutic implication, as is asserted by the cosmetic industry, it is not clear why the simple declaration that a product contains a sunscreen is not sufficient for their purposes. If an SPF declaration is for purposes of implied health benefit, as is alluded by the Australian New Zealand Standard, then this suggests these products should be regulated as therapeutic goods. If SPF is primarily required for the purposes of competitive marketing then this sets up an uneven manufacturing and regulatory playing field for those moisturisers with sunscreens, and sunscreens with moisturisers, that do elect to list on the ARTG.

Again to cite the Report:

"Sun protection is to be taken more seriously in Australia than anywhere else in the world because a coastal-dwelling, predominantly European population inhabits a country with ample sunshine and more and better accessible beaches than most. There is also the hole in the ozone layer that reduces protection. That Australia has the highest rate of skin cancer in the world is well known. School children are required to have a bottle of sunscreen and hats as part of their kit; governments have funded the Slip, Slap, Slop. campaign and children often wear 'zoot suits' at the beach to give greater protection against the harmful effects of the sun's rays."

For this very reason the SPF inherently carries connotations within the Australian context that may not be carried elsewhere in the world. While it could be argued that the public could be re-educated with regards to the relevance of SPF in terms of "cosmetic" sunscreens, the questions remains whether this will "dumb down" or "confuse" an important communication tool to consumers with regards to protection from sunburn and other damaging effects of the sun.

The Report unfortunately has not adequately explained how the labelling of sun protection and SPF claims can be maintained as "secondary" and not interpreted as co-primary, nor has it explained how such products would be adequately differentiated from other cosmetic products

that may be packaged and presented in a similar way but carry stronger claims or an SPF value above 20.

Public Health and Safety is the primary responsibility

While an approach could be taken to harmonise our approach to Europe, moving away from our present regulated approach that aligns with countries such as Canada and the US, the question should be asked as to whether this is an economic move based on grounds of facilitating imports into Australia. The proposal certainly does not provide any incentive for export of Australian sunscreen products of either a Primary or Secondary nature.

Placing these products outside the control of therapeutic goods legislation shifts the driver for market compliance upon competitor complaint. The assumptions of the Report that competitors would actively test each others products and lodge complaints under the *Trade Practices Act* 1974 assumes that cosmetic manufactures have well established testing laboratories in Australia for such purposes, or that they would pay a contract laboratory for such testing. Given the level of the market that relies upon imported product there appears little justification as to why local marketing operations for overseas cosmetic multinationals would engage in such routine testing which may prove cost-prohibitive. Compliance should not become a competitor's burden or responsibility, nor should such an important issue be relied upon competitors to notify to the authorities, by which time it's too late. SPF and stability testing is a timely and costly exercise, and it is irresponsible to assume that competitors will capture such deficiencies, which further emphasises the risk to consumer health and protection should this proposal progress. There is a significant philosophical issue at stake when the safety, quality and efficacy of a product that does convey a public health benefit is expected to be monitored by market forces.

Under a legislative approach consistent with other sunscreens, the consumer and industry can be assured that pro-active market surveillance can be undertaken by the TGA, and that products found not to be complying to the Australia New Zealand Standard, nor manufactured under adequate level of Good Manufacturing Practice, can be quickly removed from the market through a cancellation of the ARTG Listing as opposed to a slower ACCC process.

Three Critical Aspects

In coming to a position, ASMI must in the first instance take a point of view of what is the best outcome for the consumer. If we are to take the point of view that consumers can and do hold expectations that a moisturiser product with a sunscreen is capable of providing a measurable benefit against sun damage, and that SPF value is a performance value associated with this therapeutic benefit, whether it be from protection from sun burn up to protection from more serious injury – then the followings aspects are critical:

- legislatively ensuring that the integrity of SPF, UV and any related claims are not compromised;

- ensuring that the quality manufacture of all sunscreen products offering protection from UV damage are maintained at the current level; and

- that a suitable and efficient regulatory system be maintained that facilitates cost effective market entry and maintains pro-active post-market surveillance for non-

compliant products, particularly for technical breaches as opposed to those requiring a public health argument to act.

Proposed Solutions

The fact that the cosmetics industry in Australia is seeking to remove themselves from the therapeutic goods regime should come as no surprise given the following:

- the difficulties and delays in getting TGA audits or overseas authority GMP audits for cosmetic manufacturing plants. This critique has recently been validated by the outcomes of the Australian National Audit Office report into the Regulation of Non-prescription Medicines, where is has been stated:

  "Overall, the TGA's audit program is behind schedule and the majority of audits are conducted after the due date. For a sample of audits conducted in recent years, Australian audits had, on average, a due date of 16 months after the previous audit, but were conducted after 22 months. For overseas audits, the comparable figures were 21 and 30 months respectively."

  If a cosmetic manufacturer with Australian recognised GMP is only producing sunscreens as opposed to any other dermatological therapeutic good, the TGA should examine way to improve the scheduling of GMP audits or providing licencing arrangements commensurate to the low risk of the sunscreen product that enable a greater period of approval between audits.

- the double handling of active and/or excipient evaluation between TGA Office of Chemical Safety and the National Industrial Chemical Notification and Assessment Scheme for topical use ingredients.

- the unreasonable delays and inconsistencies in process for the evaluation of a new botanical/biological excipient in the Office of Complementary Medicine as compared to chemical excipients through the OTC Evaluation section. In particular members have informed us of being informed that the lack of personnel to constitute a Herbal Naming Committee is causing some of these delays. There are also issues over the amount of data being requested and naming conventions inconsistent with International cosmetic nomenclature for herbal ingredients that will only be restricted as topical excipients.

ASMI believe that rectification of these processes, in addition to increasing the flexibility for ingredient naming on labels for products meeting other international naming conventions possibly inconsistent with current AAN's, will produce greater efficiencies for cosmetics manufacturers producing sunscreens and remove present administrative burden.

If the TGA is determined to implement a strategy for diverging a class of cosmetic-sunscreen from the current arrangements, then it is critical in the first instance that detailed evidence-based criteria exists that inform the labelling and advertising conventions that provide that differentiation, particularly in light of conflicting consumer research from the medicines and cosmetic industry. This criteria has not been adequately provided as part of the Recommendations, other than on the basis of physical characteristics of packaging and arbitrary cut offs in SPF value.

Recently as part of the process of creating a new regulatory regime for health claims in food, Food Standards Australia New Zealand was provided a budget to conduct independent qualitative and quantitative consumer research to demonstrate how consumers differentiated

between labelling messages implying health benefit above that of nutrition. Given the prevention of cancer is a National Health Priority area for Commonwealth Department of Health and Aging, ASMI believes there are sound arguments for the TGA request dedicated funding from government to conduct independent consumer research in this area before creating a new regulatory regime. A well conducted study would unequivocally determine what evidence exists of consumer differentiation of products based on SPF and perceived benefit, and how Consumer Focussed Labelling principles, as alluded to in current Labelling Orders, could underpin any divergence without the risk of confusion by the consumer.

5. Antibacterial skin washes

A. Antibacterial skin washes *(including antibacterial hand wipes) should be classified as therapeutic products and described as Class II medicines.*

A significant problem with this recommendation is that currently there are a number of antibacterial skin wash products containing complementary based ingredients such as Tea Tree Oil that are by default Class I. ASMI would be against any reform that saw these complementary products reclassified as Class II under a Joint Agency.

The Antibacterial Skin Wash category may require to undergo an analysis for stratification of purpose before any regulatory reform is considered. These products can be broken down into the following categories: a) antiseptic surgical hand scrubs b) antibacterial hand preparations for use in food preparation and outpatient settings (including childcare) and c) antibacterial hand preparations for domestic use.

Because the level of claims is going to vary from "antibacterial", "antibacterial + germ kill" to "antiseptic", there are grounds for examining whether a stratification of regulatory control can be implemented that takes into account the intended use setting and level of claim. The fact that household or commercial grade disinfectants are able to make antibacterial claims, be differentiated from a Hospital Grade disinfectant and be classified as an Exempt Good indicates that there are opportunities for easing the regulatory classifications for these products.

B. *The Joint Agency, in conjunction with NICNAS, ERMA and other regulators and in consultation with stakeholders and experts in public health and microbiology determine whether the routine domestic use of hand washes containing an antibacterial agent (irrespective of the stated purposes of the product):*
(a) gives rise to the development of resistant strains of bacteria;
(b) has a deleterious effect on micro-organisms that are harmless or whose presence has, in some way, a beneficial effect in humans.

If the decision is that there is no risk to public health from the routine domestic use of hand washes containing an antibacterial agent, further consideration should be given to the appropriate classification of these products across the therapeutic / cosmetic interface.

ASMI is aware that NICNAS is already evaluating triclosan as a Priority Existing Chemical, and would not be in favour of any process that replicates the work already conducted either in Australia or overseas where consensus scientific opinion has already been reached.

ASMI is aware that the European Commission Scientific Committee on Cosmetic Products and Non-Food Products published a position on the 17 September 2002 taking account of scientific papers discussing the possible impact of the use of Triclosan on the development of anti-microbial resistance and taking into account the fact that Triclosan is not only used in cosmetics but in a wide range of consumer products, e.g. household detergents, textiles, bed linen, toys, or plastics intended for contact with food or feed. In that position they expressed no concern over the use of triclosan up to 0.3%, this being the controlled limit under Cosmetic Directive 76/768/EEC, Annex VI, part 1.

http://europa.eu.int/comm/food/fs/sc/sccp/out182_en.pdf
http://www.socgenmicrobiol.org.uk/pubs/micro_today/pdf/050403.pdf

6. Antibacterial skin cleansers (anti-acne products)
Antibacterial washes that are represented to prevent or treat acne or pimples should be classified as therapeutic products and described as Class II medicines.

Like antibacterial skin washes, ASMI believes that this is another category that should undergo further examination of regulatory reform with regard to stratification based on intent and claim.

ASMI does not believe these wash on - wash off products are necessarily most appropriately regulated as Class II medicines given their level of risk and history of safe use. There is no reason why such products with well established ingredients claiming to treat transient adolescent acne cannot be regulated as Class I medicines, with evidence being held by the sponsor and available to the TGA upon request.

There may also be capacity for consideration of prophylactic cleanser products with simple antibacterial claims, but no claims of treatment or germ kill, to be regulated as either a cosmetic or an exempt good.

The issue of Registered antibacterial/medicated bar soaps, which do not require GMP, has not been examined in either Recommendation 5 or 6 and also need consideration of regulatory reform based on stratification.

7. Toothpastes and mouthwashes

A. Desensitising toothpastes and gels *should be classified as therapeutic products and described as Class II medicines.*

ASMI members were unsure as to why desensitising toothpastes should be Class II medicines when toothpastes for the prevention of tooth decay, a more serious indication, not be classified as a therapeutic good. ASMI members believe that at the very least desensitising toothpastes should be considered as Class I medicines due to the low risk of the ingredients and application.

B. Toothpastes and gels that contain 1000 mg/kg or less of fluoride ion *and that do not make any claim (except cosmetic claims) other than preventing caries or preventing or removing plaque should not be classified as therapeutic products.*

ASMI members support recommendation.

C. Mouthwashes that contain an antibacterial substance *for freshening the breath or for fighting plaque and where no therapeutic claims are made should not be classified as therapeutic products.*

Given the concern over antibacterial substances in previous recommendation, this recommendation would appear largely inconsistent. A concern exists that if a claim other than freshening the breath or fighting plaque were made the good would be regarded as a Class II good, when Class I would be more appropriate.

D. Mouthwashes that contain 220 mg/L or less of fluoride ion *and that do not make any claim (except cosmetic claims) other then preventing caries or preventing or removing plaque should not be classified as therapeutic products.*

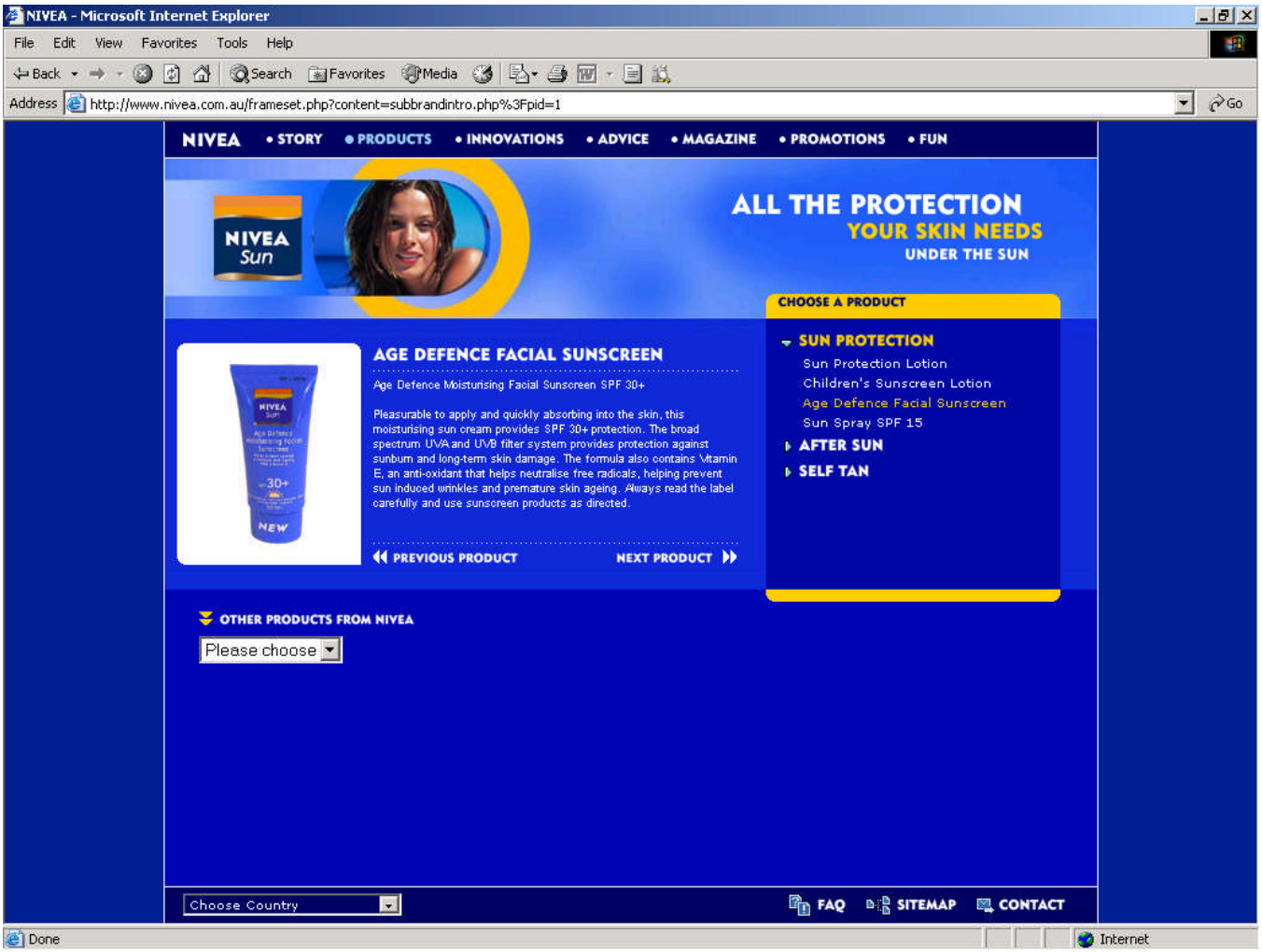
ASMI members support the recommendation

8. Other product categories that may be candidates for reform

Personal lubricants *should be classified as therapeutic products, irrespective of any representations that are or are not made.*

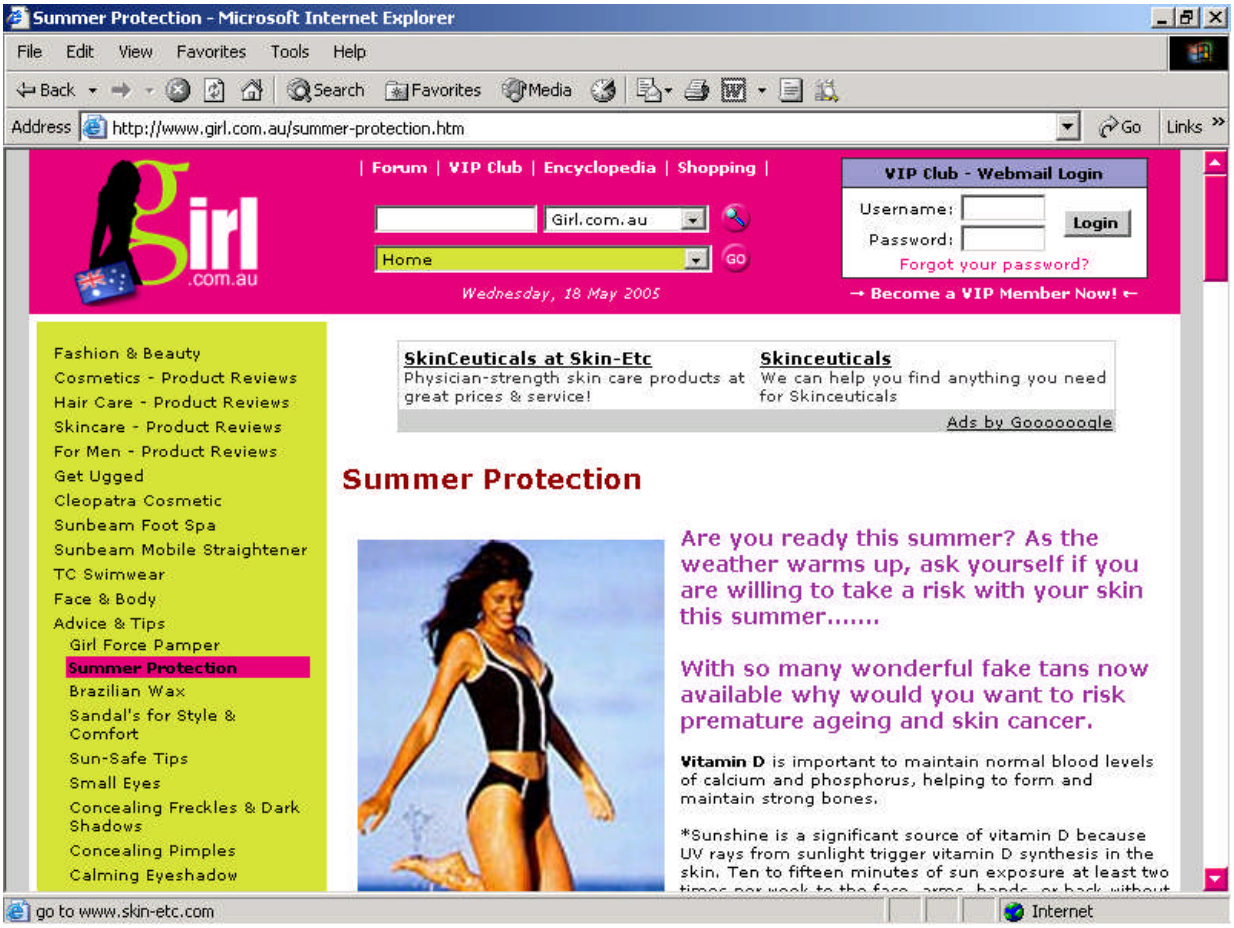
ASMI members are unsure as to the scope of this recommendation and whether further review of this category is required before recommendations are adopted. While any personal lubricant with potential to be used for use in a human orifice should be regulated, it is not clear the effect this recommendation would have upon other non-water based gel lubricants such as Vaseline petroleum jelly with a use other than the aforementioned intent.

Attachment 1



Claim for "Age Defence Moisturising Facial Sunscreen" from Australian Nivea website

"Pleasurable to apply and quickly absorbing into the skin, this moisturising sun cream provides SPF 30+ protection. The broad spectrum UVA and UVB filter system provides protection against sunburn and long-term skin damage. The formula also contains Vitamin E, an anti-oxidant that helps neutralise free radicals, helping prevent sun induced wrinkles and premature skin aging."



From http://www.girl.com.au/summer-protection.htm

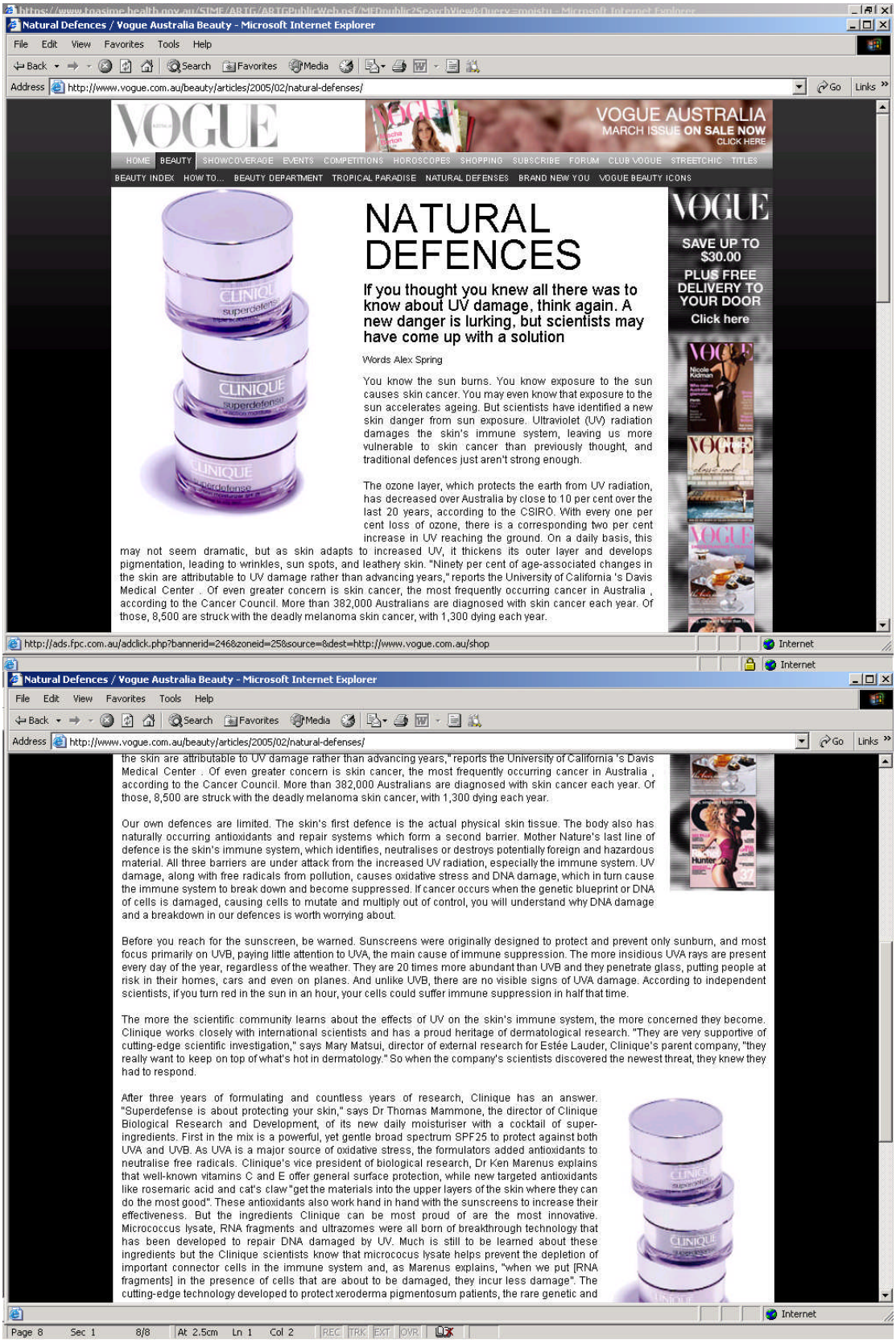
VASELINE INTENSIVE CARE - Daily Sun Defence SPF 15

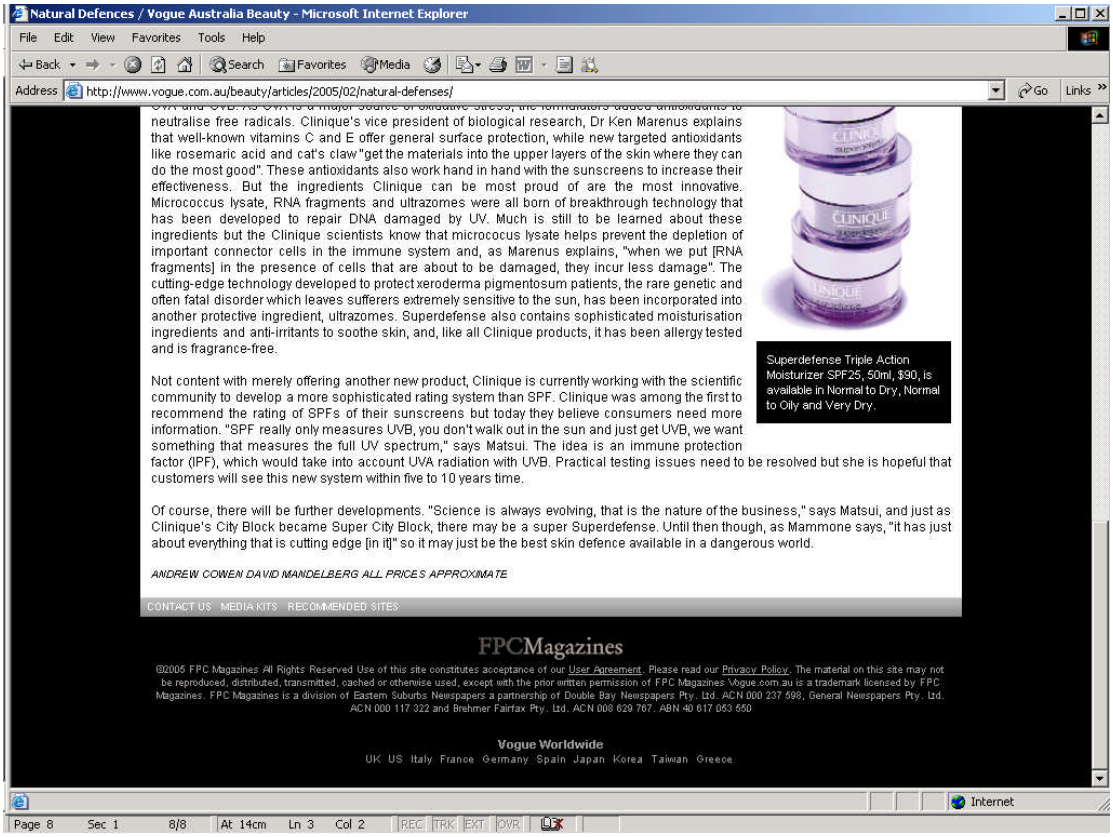
For healthy, glowing skin all over your body, you have to protect yourself and be on the body defensive. Now, all over sun protection can easily become part of your usual daily moisturising routine with new Vaseline Intensive Care® Daily Sun Defence with SPF 15.

A sunscreen should be used on our body every day, but doing so can be a hassle - it takes time and sunscreens are often greasy.

Daily Sun Defence is a unique innovation that combines a light, non-greasy Vitamin E enriched moisturiser with UVA and UVB sunscreens to moisturise your skin and protect it from the sun's damaging and drying rays. It only takes one easy step, so there's no need to apply a separate sunscreen. Your skin is left feeling soft, smooth and fresh.
RRP $6.29 for 200mL. Available at supermarkets, pharmacies and variety stores nationally.

Attachment 2

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neutralise free radicals. Clinique's vice president of biological research, Dr Ken Marenus explains that well-known vitamins C and E offer general surface protection, while new targeted antioxidants like rosemaric acid and cat's claw "get the materials into the upper layers of the skin where they can do the most good". These antioxidants also work hand in hand with the sunscreens to increase their effectiveness. But the ingredients Clinique can be most proud of are the most innovative. Micrococcus lysate, RNA fragments and ultrazomes were all born of breakthrough technology that has been developed to repair DNA damaged by UV. Much is still to be learned about these ingredients but the Clinique scientists know that micrococus lysate helps prevent the depletion of important connector cells in the immune system and, as Marenus explains, "when we put [RNA fragments] in the presence of cells that are about to be damaged, they incur less damage". The cutting-edge technology developed to protect xeroderma pigmentosum patients, the rare genetic and often fatal disorder which leaves sufferers extremely sensitive to the sun, has been incorporated into another protective ingredient, ultrazomes. Superdefense also contains sophisticated moisturisation ingredients and anti-irritants to soothe skin, and, like all Clinique products, it has been allergy tested and is fragrance-free.
Superdefense Triple Action Moisturizer SPF25, 50ml, $90, is available in Normal to Dry, Normal to Oily and Very Dry.
Not content with merely offering another new product, Clinique is currently working with the scientific community to develop a more sophisticated rating system than SPF. Clinique was among the first to recommend the rating of SPFs of their sunscreens but today they believe consumers need more information. "SPF really only measures UVB, you don't walk out in the sun and just get UVB, we want something that measures the full UV spectrum," says Matsui. The idea is an immune protection factor (IPF), which would take into account UVA radiation with UVB. Practical testing issues need to be resolved but she is hopeful that customers will see this new system within five to 10 years time.
Of course, there will be further developments. "Science is always evolving, that is the nature of the business," says Matsui, and just as Clinique's City Block became Super City Block, there may be a super Superdefense. Until then though, as Mammone says, "it has just about everything that is cutting edge [in it]" so it may just be the best skin defence available in a dangerous world.
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Attachment 3

Attachment 4

10 May 2002

Skin cancer warnings 'need revision'

By Lydia Bell

The battle to reduce Australia's high incidence of skin cancer would benefit from a rethink of the messages put out in public education campaigns, according to one of the University's health specialists. Professor Bruce Armstrong, who is presenting a series of lectures at the University on skin cancer, said sun-protection campaigns should be aimed primarily at parents, who were above all concerned with the health of their children.

Protection throughout life should also be promoted, he said. While exposure in childhood determined the potential for skin cancer, sun exposure in later life decided the extent to which this potential was realised. Research in Europe studying the relationship between adult and childhood exposure revealed that "one multiplies the effect of the other", he said.

Professor Armstrong, head of the School of Population Health and Health Services Research, has looked in his lectures at our understanding of skin cancer, sun exposure patterns and current and future means of preventing the disease. He said reducing the time spent exposed to the sun in childhood was a strong factor in skin cancer prevention. This was reflected in the fact that migrants who arrived in Australia as adults were two-thirds less likely to develop the disease than Australian-born residents. Indoor workers who spent only 10 to 20 per cent as much time in the sun as outdoor workers should concentrate on covering up on holiday and at play, he said. "Telling someone to put on a hat when they catch the bus at 7.30 in the morning is not going to work. If we don't put out messages that sound inherently sensible, we are in danger of people doing nothing at all," he argued. Professor Armstrong recently warned that people who worked indoors were at greater risk of contracting skin cancer than outdoor worker such as gardeners. Melanomas were most commonly found in intermittently exposed skin, he said, and the most intensive targeting should be aimed at sun-sensitive people.

"Health educators are cautious about this kind of targeting because less sensitive people might take greater risks in response," he said. But he added that exposure to the sun's UV rays brought benefits that could be weighed against the harms. They included Vitamin D production and possible protection against breast and prostate cancer, suppression of autoimmunity, and a greater sense of well being.

The point at which the harm exceeds the benefit was dependent on the individual and their skin's sensitivity to the sun, he said, so that less sensitive people could deal with a higher level of sun exposure.

People could check UV index forecasts for their area to help them know when the levels were unlikely to cause them harm. But he warned that giving people an understanding of how to use these forecasts effectively could present "something of a challenge to communications experts".

"The messages we would need to get across are seen as too complex for most people. Or are they? Have we even tried? Most people already have an implicit sense of when it is 'safe' to be in the sun."

He said sunscreen should have the broadest possible spectrum, and be used to protect skin when it was exposed to the sun. It should not be used to lengthen the time spent in the sun, as this could increase the risk of melanoma.

Professor Armstrong said there were still a number of areas that needed to be researched to give people better advice on how to live safely with the sun. These included how best to educate people to use the UV index effectively, the possibility that melanoma risk was increased when sunscreen was used to extend the time spent in the sun, and whether sunscreen used later in life could reduce the risk of melanoma.

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Last updated: 10-May-2002

http://www.usyd.edu.au/publications/news/021005News/1005_cancer.html