THE AUSTRALIAN SOCIETY OF COSMETIC CHEMISTS

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Affiliated with the IFSCC

May 19, 2005

Dr Margaret Hartley
Director, NICNAS

Mr Pio Cesarin
Director, Non-Prescription Medicines Branch

Dear Margaret and Pio,

Re: The ASCC response to the 'Review of the regulation of products at the interface between cosmetics and therapeutic goods'.

Please find hereunder the submission of the ASCC on the above mentioned matter.

The Australian Society of Cosmetic Chemists is a professional scientific organization that promotes the advancement of the theory and practice of the science and technology of cosmetics, toiletries and perfumery. Our membership includes scientists and technicians involved in the development, manufacturing and other individuals who are working or interested in the cosmetics, toiletries and perfumery industry. The society has been in existence for more than fifty years and is a member of with the International Federation of Cosmetic Scientists.

The ASCC is a stakeholder involved in all aspects of the contents of the Newgreen report so please find hereunder our comments compiled by members of our Technical Committee and applied by way of the Principles as per Appendix I (which are the same as the Reports).

Gavin Greenoak
President
ASCC

Antiperspirants

The ASCC supports the recommendation of the Newgreen Report to classify antiperspirants with organic or inorganic actives of Aluminium, Zirconium or Zinc not as therapeutic goods (and therefore as cosmetics) and antiperspirants containing other new actives should be classified as Class II.

The ASCC further recommends that these excluded goods should be regulated as cosmetics with regards to labelling, claims (provided they comply with the definitions and guidelines of cosmetics) and excipients. This would satisfy the principles of 1, 4, 5 and 6.

Recommendation: The ASCC supports the Newgreen Report's recommendation to maintain the status quo of the category (i.e. that Antiperspirants derived from organic and inorganic salts and derivatives of Aluminium, Zinc and Zirconium only should not be classified as therapeutic goods under the Joint Agency)and further recommend:	
(a)	that these excluded goods become cosmetic products with regards to their regulatory categorisation

Anti-dandruff

The ASCC support recommendation that Antidandruff product (shampoo, hairdressing or lotions etc) should continue to be classified as drugs. Anti-dandruff product if unscheduled will be exempted from registration or listing and also exempt from manufacturing licensing.
The Principles applied are 1, 4, 5, and 6.
New active ingredients will continue to be evaluated by TGA for safety and efficacy and NDPSC for Poison Scheduling when used in registered product. NICNAS will evaluate unscheduled new active/ingredient.
In essence reform is not required re the status quo for antidandruff product classification and new actives. Given the current system works effectively and it addresses both registered and exempt product. This approach meets principle 1 reform guideline.
ASCC recommends there should be a clear direction as to who regulates ingredient used as excipient in Exempt Products in general. And the regulating body should be explicitly referred to in the recommendation so there is no confusion within the industry.

Under current system all ingredients have to be on the ARTG and regulated by TGA as it is an Exempt Drug not Excluded Goods or Cosmetics. ASCC recommends excipient (including fragrances) used in Exempt Goods to be regulated by NICNAS as there is more ingredients on the AICS for public use versus chemicals on the ARTG. NICNAS evaluation includes both occupation/public health and environmental impact in addition to the toxicity data evaluated by TGA. ASCC further recommends that the sponsor should be allowed to use excipients listed on either the ARTG or AICS for Exempt Drugs as the chemical may have been evaluated as safe or has been on the market without adverse affects. This approach meets principles 1, 4, 5 and 6 reform guidelines

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In addition, ASCC recommends the option of using Cosmetic Labelling for Exempt Anti-dandruff product provided active ingredient and its concentration are captured on the pack. Consumer could

benefit from this because of full ingredient listing requirement in cosmetics versus drug. This approach meets Principle 1.

Recommendation: The ASSC supports the Newgreen Reports recommendation with the status quo of the category as an exempt therapeutic good except for new or scheduled actives, however further recommends:	
(a)	that excipients be used from either ingredients currently on the ARTG or AICS
(b)	that new excipients be regulated by NICNAS
(c)	that cosmetic labelling be used except for quantifying and naming the actives in the exempt products.

Sunscreen-Containing Products

Australia has one of the highest skin cancer rates in the world with 1 in 2 Australians being diagnosed with the disease some time during their life. Some 5.6 million Australians out of a population of 20 million will get sun-burnt in one year.[1] 374,000 Australians are diagnosed with non-melanoma skin cancers every year and 360 die, while 8,500 new cases of melanoma are diagnosed every year and 1,000 Australians die of the disease.[2] The cost to the community in medical resources and the human toll is enormous. Sunscreens are an important aspect of the overall strategy to reduce this horrific toll as highlighted by the 'Slip, Slop, Slap' campaign. Sunscreens are rightly regulated as therapeutic goods and viewed by the consumer as such. The SPF label, as a result of several decades of education programs, is iconic and instantly associated by the consumer in Australia with a therapeutic product. It would be the height of irresponsibility to allow the significance of that symbol to be lost, as it would be if cosmetic moisturiser products were allowed to use that symbol.

CONSUMER PERCEPTION.

The average consumer would be totally unaware of the difference between a secondary sunscreen and a primary sunscreen and it is totally unrealistic to expect the consumer to differentiate between a sunscreen and a moisturiser once both are labelled with an SPF. The implications for sun protection are profound in that one product is a cosmetic moisturiser with added sunscreen, the other a therapeutic sunscreen. No one would want the consumer to use the cosmetic in place of the primary sunscreen, yet this proposal is setting the consumer up to do just that, this is certainly contrary to the stated primary consideration of the review to 'maintain and enhance the protection of public health, safety and environmental standards'[3]

SPF: THERAPEUTIC CLAIM.

The review states 'One industry organization indicated that merely citing the SPF on the label was a therapeutic claim sufficient to bring a product so labelled within the Therapeutic Goods Act 1989. The SPF is a statement of fact determined from standardised tests conducted by a laboratory on the particular formulation. It does not, of itself, promise any therapeutic benefit'.[4]
Indeed the first sentence of this quote remains the Australian Society of Cosmetic Chemists (ASCC) position, and it is agreed that the SPF is arrived at using a standardised test, importantly, one with a human biological indicator as an end-point. Under current regulations this sentence is correct, citing of the SPF **does** make the product a therapeutic good and indeed products may not make therapeutic claims unless included in the Australian Register of Therapeutic Goods, and the TGA position is no different. The ELF system allows SPFs above 4 to be the only **therapeutic** indication on the listing submission.
Furthermore, the majority members of the TGACC in their April, 2005 meeting endorsed the position that SPFs are therapeutic indications for advertising purposes.
Also the Australian/New Zealand Standard indicates that SPF is an indicator of protection ('against serious long term **ill** effects'- foreword) from the sun's damaging affect to skin, including sunburn and other effects from UVA and UVB radiation. The ASCC contends that helping to prevent sunburning is a **prophylactic therapeutic** claim.
Therefore SPF does of itself promise a therapeutic benefit.
So what point is the report trying to make?

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[1] Sunsmart - Skin Cancer Statistics for Australia. URL: http://www.sunsmart.com.au/s/facts/stat_aus.htm
[2] The Cancer Council Australia. URL: http://www.cancer.org.au/content.cfm?randid=960742
[3] 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. (pV).
[4] 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. (p65, 66).

It seems to the ASCC that by simple mistake the review is downgrading of the value of the SPF claim.

Ostensibly then, if the SPF of itself does not 'promise any therapeutic benefit' then the case for Primary Sunscreens (nowhere in the review is it suggested it will be allowed to be identified as such) is undermined.
Thus, if (Moisturiser + SPF) is not a therapeutic, then neither is (Sunscreen + SPF).
If the SPF does promise a therapeutic benefit, then it must attract a therapeutic good status.
SPF means that the product will protect the skin from sun induced damage to a certain level, in other words that it is a sunscreen, as well. That a product is being purchased as a moisturiser in no way hides that it is also in fact a sunscreen, and promises sun protection.

PRIMARY OR SECONDARY.

Sun protection is a serious business. Given that the recommendation explicitly states against any mention of primary use, the SPF labelled moisturiser WILL be used as a sunscreen as well, as the SPF invites this use. The question of primary or secondary purpose in the presence of this labelling must be purely speculative since BOTH are invited equally. This is clearly against the public interest and again clearly contradicts the stated primary guiding principle of the review.
Secondary sunscreens are first and foremost cosmetics. That is the function their sponsors intend for them. The fact they contain sun screening agents is perceived as an additional benefit. To label a moisturiser with an SPF will highlight an aspect of the product that is not its' primary role. Sunscreens in the Australian context play far too important a role in the well being of the user to be relegated to a secondary position. There can be little doubt a consumer using a moisturiser labelled SPF 20 will consider the use of any further protection as provided by a primary sunscreen to be unnecessary. Further, if the product is being purchased and is used (sparingly) as a moisturiser, then it cannot deliver on the promise of sun protection as stated by the SPF.[5]

CONSEQUENCES OF SUGGESTED CHANGES.

Although the ASCC is concerned by the inclusion in the review of the incidental comment 'The absence of basic sanitary controls on cosmetic manufacturing premises in Australia was noted. No recommendation was made on this matter because it applies to the manufacture of all cosmetics and not just the classes of goods that are the subject of the Report'[6] and wonders as to the motives in making this statement. However to follow the statement through and putting any concerns aside, if the recommendations of the review are accepted then it will be in these 'perhaps unsanitary' (for that is the implication of the above statement) premises where at least some of the local manufacturing of moisturisers will take place.
Currently sunscreens can only be manufactured in Australia by manufacturers licensed by the TGA under the code of GMP. Secondary sunscreens are cosmetics and as such in Australia and New Zealand can be manufactured by anyone, totally unregulated under any conditions. As a result there may be no assay of actives at the end of the manufacturing process, no Quality Assurance and no guarantee that on a batch-to-batch basis the product is providing the claimed protection. Under the present arrangements any product claiming an SPF must use ingredients and actives listed and limited by the TGA. These limits do not apply to unregulated cosmetics and some manufacturers could use concentrations of active agents beyond the limits set by the TGA.
The report suggests industry participation in this area will solve problems such as these and others and while this MAY prove to be the case in Australia, it is a somewhat facile argument when it comes to some of our third world neighbours. Unfortunately and increasingly, due to cost constraints and various government schemes this is where a lot of cosmetics sold in Australia are now being produced. And yet once again, this goes straight to the heart of the guiding principles of the review – and the consumer has the right to expect that in this important area of public health that they are getting what the label

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[5] AS/NZS 2604:1998. Sunscreen products-Evaluation and classification. Appendix B. B4.5 Application of products. (p19).
[6] 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. (pVI).

says they are getting. Further a moisturiser used sparingly cannot deliver the promise of the SPF on the label and this will be directly and incontrovertibly misleading.

The point must be stressed that unless a sunscreen is manufactured under the code of GMP for therapeutic goods, the consumer has no guarantee that it contains the key actives that it says it contains, does not contain harmful substances, performs as it claims to perform, continue to confer these benefits through-out its shelf-life, and that the TGA ensures that it does so by a series of post-market surveillance. Without these essential checks that are required for a therapeutic good, but not for a cosmetic, the effectiveness of the sunscreen cannot be assured. This goes to the heart of the principle I as to safety, efficacy and quality of products.

PURPOSE OF THE GOODS IN THE MARKET TEST.[7]

The report examines a selection of goods on the NZ market, both legitimate and otherwise, and extends this anecdotal evidence to eventually state with some resolve that the cut-off figure for cosmetic products had better be 20 as this recognises market realities.
Market realities?
Market realities that have already been pointed out to be questionable use of ethics by the report itself. The point has already been made regarding the presence of SPF on labels and the effect this will have in the Australian market place, i.e the mere presence of the SPF value on a label will immediately cause said product to be considered as a sunscreen.
The ASCC strongly believes that this point is vital and invalidates every one of the review's arguments in this section to justify the inclusion of the SPF value on the label of moisturisers.
The report opposes additional mandatory wording on the pack of secondary sunscreens that might dilute the marketing claims of the cosmetic manufacturers. This is clearly indicated by the opposition to mandatory phrases such as 'use a primary sunscreen when in direct sunlight.' This simply highlights that the recommended changes to secondary sunscreens are marketing driven rather than by genuine concern for the well being of the consumer, as all Australians should only use primary sunscreens when spending time in the sun, and once again we arrive at the principle 'primary consideration will be to maintain and enhance the protection of public health.....'.

IN SUMMARY

1. Cosmetics

While the input of the Joint Agency into the updating of the current cosmetic guidelines is highly recommended, the policing of the 'Cosmetics Claims Guidelines' should be left to the ACCC. Indeed the report itself makes mention of a number of times where breaches of the Trade Practices Act have been effectively prosecuted.[8] The ASCC contends that there are many stakeholders with regards to this issue and the Joint Agency is only one of the stakeholders, therefore the current authority the ACCC should be one responsible for the cosmetic guideline.

2. Sunscreen recommendations

A. The ASCC supports this proposal with the following reservation, the definition of the word "acceptable" in the phrase "acceptable international standard" needs to be more fully explained (e.g. acceptable to whom?), the Australian/New Zealand Sunscreen Standards Committee – CS42, is the logical arbiter.
"The Australian/New Zealand Sunscreen Standard is cited in the Therapeutic Goods Act and so has regulatory authority. Except in the USA, the overseas standardised methods are merely guidelines and have no legal status and so cannot be enforced".

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[7] 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. (p62-67).
[8] 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. (p65).

B. The ASCC supports this recommendation, provided that no SPF is displayed.

C. The ASCC supports the status quo in this area and for the reasons already detailed cannot support the use of a SPF number being displayed on non-therapeutic cosmetic moisturisers.

3. The ASCC position.

The ASCC, as a member based association completely unaffiliated in any way with industry groups, umbrella organisations and free of any allied marketing and company links has always strived to consider the position of public safety as a matter of priority. It is hard for the Society to understand the findings of the report given the primary consideration of public safety listed as one of the guiding principles of the review.
The moisturising product which states 'includes sunscreen' completely fulfils, and without confusion or risk, the primary purpose for purchasing the product with an additional sun protective capability. That the SPF is omitted ensures this clarity of purpose. Indeed the report correctly makes the very same point 'the exclusion conditions are intended to maintain a clear distinction between products that people rely on for moisturising (with incidental sun protection capacity) and those products for prevention of sunburn and skin cancers.'[9] (a therapeutic claim, no less – but then SPF is simply a standardised test).

However, this is not to say that the current listing of these products' system does not have its problems. The major problem with the current system is the naming and evaluation of the excipients. Sunscreen products may contain excipients that are not on the ARTG and since these products may be seasonal products timing is of importance.
The problem with naming is that there are two TGA naming committees one for chemical /biologicals and one for herbals. Many sunscreens contain herbal/algal extracts in very small amounts for skin conditioning purposes and the Herbal naming committee can take up to nine months to properly identify, evaluate and have available on the ARTG new herbal excipients.
Furthermore some sunscreen products may have many herbal excipients which all have to be evaluated at a considerable cost.
The ASCC recommends that the naming of herbal ingredients for topical sunscreen application be treated differently from those considered for oral application perhaps referencing its monographed source and for topical application use only. Also to have this completed at least the naming of it within two weeks.
Also some of the warnings for use of certain ingredients (eg creatine) which apply for oral application should not apply for topically applied sunscreens.

Recommendation:
The ASCC does **not** support the Newgreen Report's recommendation, and recommends that all sunscreens retain their current regulatory status whether 'primary or secondary'. However the ASCC further recommends that changes be made to facilitate the current therapeutic good processes for sunscreens.

[9] 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).

Antibacterial Hand Washes

The ASCC agrees with the recommendations in the Newgreen report and recommends that consideration be given to making some Antibacterial Hand Washes containing common much used ingredients such as Triclosan, Chlorhexidine and some Quaternium ammonium chlorides be changed to Class I categories due to their long term usage and having no known adverse affects.
The Principles applied are 1, 4, 5, and 6.

Recommendation: The ASSC supports the Newgreen Reports recommendation with the status quo of the category, however further recommends:	
(a)	that common and non-scheduled actives with low or medium level claims be reclassified to Class I products.

Acne Washes

The ASCC believes that Acne products containing unscheduled ingredients and that make no therapeutic claims such as anti-bacterial or treating acne should be classified as cosmetic products.

Anti-acne products that utilise unscheduled commonly used actives and only make general or medium level claims should be reclassified as Class I products. It would be a waste of OTC registration branch to evaluate products and claims which have been evaluated many times with the same acceptable results.

Any new anti-acne actives or scheduled active and products with high level claims should remain as Class II medicines.

The Principles applied are 1, 4, 5, and 6.

Recommendation: The ASSC recommends a three tier system for Acne washes products:	
(a)	Cosmetics for non-scheduled and commonly used actives with cosmetic claims
(b)	Class I containing non-scheduled and commonly used actives with general or medium level therapeutic claims
(c)	Class II containing scheduled and/or with high level claims.

Toothpastes and Mouthwashes

The ASCC agrees with the Newgreen Reports recommendations and are based on Principles 1, 4, 5, 6.

Recommendation:
The ASSC agrees with the Newgreen Report.

Personal Lubricants

The ASCC recommends that all personal lubricants whether for medical or other purposes should be Class I medical devices that lubricants should have GMP acceptable according to the Essential Principles and that substantiation of therapeutic claims should be held by the supplier.

Recommendation:
The ASSC agrees with the Newgreen Report.

The ASCC wishes to thank the TGA, MEDSAFE, NICNAS and Mr. Newgreen for the opportunity to comment on the report. With the important principle of transparency in view, and underscored by the policy of "full cost recovery", we await the reasoned consideration of our informed submission respecting these issues as they affect our membership and the Australian community.

Yours sincerely,

For and on behalf of the Technical Committee of the ASCC

Gavin Greenoak.

President

Appendix I

The Principles:

1. The primary consideration will be maintain and enhance the protection of public health, safety and environmental standards, consistent with the objectives of the Therapeutic Goods Act 1989, The National strategy for the quality use of medicines, the Industrial Chemicals (Notification and assessment) Act 1989 and the Trade and Practices Consumer Product Information Standards (cosmetics) Regulations 1991

2. Regulatory reform will be undertaken in accordance with 1997 Council of Australian Government (COAG) principles and guidelines.

3. Regulatory reform must be consistent with the Agreement between the government of Australia and the government of New Zealand for the establishment of joint scheme for the regulation of therapeutic products.

4. Recognising that cost-recovery is Australian Government policy for medicines and chemicals, all costs associated with reform activities will be cost-recovered from industry.

5. Government and industry acknowledge the need for a national approach to ecologically sustainable chemicals management and regulation.

6. There will be no automatic listing ("grandfathering") of unassessed chemicals onto the Australian Inventory of Chemical Substances (AICS) or the Australian Register of Therapeutic Goods (ARTG)