AHII

27 April 2005

Cosmetic Review Process
NICNAS
Department of Health and Aging
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

By email: cosmetic_review@nicnas.gov.au

REVIEW OF THE REGULATION OF PRODUCTS AT THE INTERFACE BETWEEN COSMETICS AND THERAPEUTIC GOODS; 18TH MARCH 2005, PREPARED FOR THE TGA BY DAVID B NEWGREEN

Dear Sirs

Please find below comments from the Australian Health Industry Incorporated (AHII) on the NICNAS TGA review of the interface between cosmetics and therapeutics. The AHII represents members with an interest in these areas.

Specifically :

SUNSCREEN CONTAINING PRODUCTS

In Australia products claiming a Sun Protection Factor (SPF) are regulated as therapeutic goods. Several decades of use of the SPF claim exclusively on regulated products and extensive education programmes have led to the SPF becoming iconic and instantly associated by the consumer in Australia with a quality therapeutic product whose principal purpose is to protect the skin from the harmful effects of solar radiation. A cosmetic product may contain a sunscreen and state this on the label, but unless the product is Listed by the TGA, it is prohibited from making SPF or therapeutic claims.

The recommendation in the Report is to allow cosmetic products containing a sunscreen to claim an SPF of up to an SPF of 20 on their label, although their primary function is something other than sun protection. This is strongly opposed by the AHII for the following reasons:

Australian Health Industry Incorporated
336 Glen Osmond Road, Myrtle Bank, SA 5064
Ph/Fax: (08) 8 379 2172

I

Primary sunscreens or secondary sunscreens Listed with the TGA are distinguished from cosmetics containing sunscreens by the fact that they carry an SPF claim on the label. Primary sunscreens can only be manufactured for Australia under the code of GMP in premises licensed or approved by the TGA. All manufacturers of products claiming an SPF are therefore subject to inspection by the TGA or an equivalent regulatory body and required to justify claims, product stability and meet high standards of manufacture and Quality Assurance as well as have recall protocols in the event of problems.

With the exception of Europe, most countries of the world including Australia do not require cosmetics to meet even the most basic of manufacturing standards. Further, under the present arrangements any product claiming an SPF must use ingredients and actives prescribed by the TGA. TGA guidelines also limit the amount of any one active that may be used for safety reasons. For instance, the sunscreening agent octylmethoxycinnamate can only be used according to the TGA guidelines to 10% w/w maximum. These limits do not apply to unregulated cosmetics.

Further, ingredients not listed by the TGA, including some sunscreen actives, may be used in cosmetics bypassing the strict controls the TGA has imposed for product safety. There is no evidence that competitor monitoring will ensure compliance to any standards and this has previously proven to be ineffective in the cosmetic/therapeutic boundary in Australia.

Under the proposed changes, an SPF claim of up to 20 may be made for cosmetics. Consumers do not differentiate a primary sunscreen with an SPF claim from a cosmetic with an SPF claim. To them, the SPF claim represents the performance and quality of the product. A claimed SPF of this magnitude, in an unregulated cosmetic product marketed in Australia, would present an unacceptable risk to the consumer as sunscreens are used over large parts of the body, often for long periods of time and daily.

The NZ Health authorities have recognised this danger and want to limit the maximum SPF claim for cosmetics containing sunscreens to 15. In the view of the AHII even this is too high. It was only in 1998 and after lengthy debate that Standards Australia agreed to lift the maximum allowed SPF claim from 15+ to 30+ for primary sunscreens. Some bodies still recommend only the use of SPF 15 sunscreens; however it is now acknowledged that this is insufficient protection, particularly with most consumers applying too small an amount of sunscreen for the rated SPF to be achieved. With low viscosity cosmetic moisturisers, this risk becomes even greater, particularly as there are no specific application instructions or rates for most cosmetics.

The AHII contends that the proposed changes for the above reasons would confuse consumers who could then use an unregulated product as their only means of sun protection. There is no mechanism proposed that would adequately ensure they

Australian Health Industry Incorporated
336 Glen Osmond Road, Myrtle Bank, SA 5064
Ph/Fax: (08) 8 379 2172

could clearly differentiate these unregulated products from the regulated primary sunscreens. The cosmetics would, because of low compliance costs, be cheaper to produce, hence pricing could encourage consumers to purchase and use these uncontrolled products as their main sunscreens when playing sport or working outdoors. This would pose a serious and unacceptable health risk for consumers.

Furthermore, it would become an unequal playing field for primary sunscreen manufacturers saddled with additional costs, Good Manufacturing Practice Code compliance costs and more restricted access to new sunscreening agents compared to the cosmetics. This will discourage the development in Australia of better sunscreen products.

In addition primary sunscreens are required to carry warnings to avoid over-exposure to the sun, ie to encourage responsible use of the products. We see no provision for this sort of warning to be carried on the cosmetics containing sunscreens.

The AHII recommends the current regulations pertaining to cosmetics containing sunscreens remain unchanged.

ANTI-BACTERIAL WASHES:

In Australia hand washes which are labelled as "anti-bacterial" are regulated as therapeutic goods and fully evaluated by the TGA. They must have demonstrated efficacy, be made by a TGA licensed manufacturer and labelled in accordance with the Therapeutic Goods Labelling Order. Products containing an anti-microbial but whose labels do not contain the words "anti-microbial" or "kills germs" are considered cosmetics and are unregulated.

The Report recommends that "anti-bacterial skin washes" (including anti-bacterial hand wipes) should be classified as therapeutic products and described as Class II medicines.

In its discussion, the Report uses the term "anti-bacterial hand washes" when describing products containing an anti-microbial but make no label claim, as well as for products labelled as "anti-microbial". It is not clear therefore, as to whether the definition of the term "anti-bacterial skin washes" the Report is using in its recommendations, refers to products containing the word "anti-bacterial" in labelling, or the mere inclusion of an anti-bacterial agent in the formulation, or both. This lack of clarity could lead to the interpretation that the mere inclusion of an anti-microbial in a formulation means the product is a therapeutic.

Australian Health Industry Incorporated
336 Glen Osmond Road, Myrtle Bank, SA 5064
Ph/Fax: (08) 8 379 2172

"Anti-microbial agents' such as chlorhexidine and triclosan may be used in the formulation of cosmetic products in lower concentrations as part of the preservative system for that product. Therefore, while the product contains an "anti-microbial agent" it is not an anti-microbial product. The proposed requirement would make a purely cosmetic product into a therapeutic simply because of the preservative system used.

In the view of the AHII, the labelling of a product as anti-bacterial makes that product a therapeutic good and as such a Class II medicine. In this we agree with the Report. However, the AHII believes that products which include an anti-bacterial agent but make no anti-bacterial label claim should remain exempt until there is consensus on the question as to whether these products present a public health issue or not.

The AHII therefore supports the proposal subject to the clarification that inclusion of an anti-bacterial agent does not on its own classify the goods as Class II medicines.

The AHII would be pleased to provide further comment on this submission if required.

Yours sincerely

Richard Blake

RICHARD S BLAKE
CHAIR
REGULATORY & TECHNICAL AFFAIRS COMMITTEE

Australian Health Industry Incorporated
336 Glen Osmond Road, Myrtle Bank, SA 5064
Ph/Fax: (08) 8 379 2172