DSAA
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19 July 2005

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

Dear Pio,

Re: Review of the Regulation of Products at the Interface between Cosmetics and Therapeutic Goods (Newgreen Review)

During the last two months, on behalf of the Association, I have discussed the Newgreen Report with the undermentioned persons representing relevant industry bodies: -

Mr John Woods:	Cosmetic Toiletry and Fragrance Association of Australia (CTFA)
Mr Garth Wyllie:	Cosmetic Toiletry and Fragrance Association of New Zealand
Ms Bronwyn Capanna:	Accord Australasia
Ms Jessimine Stewart:	Medsafe New Zealand

I have assisted with the preparation of the CTFA submission dated 16 May 2005 and I am conversant with the ten recommendations contained in that submission. A summary of these recommendations is attached.

Members of this Association have a strong interest in the matters covered in the Newgreen Report. In the calendar year 2004, DSAA members' sales of Cosmetics, Skin Care and Personal Care products were $377,636,000.

A list of Association Members is attached.

I advise that this Association supports the CTFAA comments in relation to the recommendations listed in the summary attached.

Sincerely,

Les Dell
Executive Director

Attachments

H:\Legal and Government\CTFA Review to Cesarin- Newgreen Report Jul 05.doc

Direct Selling Association of Australia Inc

Response to the Newgreen Report

Recommendations:

Recommendation 1:

Cosmetic Claims Guidelines

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.

Recommendation 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.

Recommendation 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[1] from licensing; and

(b) The premises where the product is manufactured should be exempt from licensing.

Recommendation 4A:

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.

Recommendation 4B:

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

Recommendation 4C:

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 moisturisers that are secondary sunscreens.

Recommendation 5:

Antibacterial skin washes

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

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.

Recommendation 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.

Recommendation 7:

Toothpastes and mouthwashes

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

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.*

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.*

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.*

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.

Sydney
23 May 2005

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Enjo Pty Ltd

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Mr Les Dell

Mr Val Fittler

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Mrs Imelda Roche

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