



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

July 2005

**AUSTRALIAN DRAFT REVIEW OF POLICY FRAMEWORK FOR REGULATING
PRODUCTS AT THE COSMETIC THERAPEUTIC INTERFACE**

SUMMARY OF RESPONSES TO THE RECOMMENDATIONS

Eighty five responses were received. Respondents were asked to indicate whether they were prepared to have their submission made available on the TGA and NICNAS web sites. Eight did not wish to have their submission published – these have been included in the summary below but identifying details have been removed.

The full responses are attached. Seven responses have been omitted – these are the ones that did not want their submission published. The eighth respondent wished to remain anonymous but did not object to publication – this document is included but identifying details have been removed.

RECOMMENDATION 1 – GUIDELINES

Cosmetic 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.

RESPONDENT	RESPONSE
ACCORD	ACCORD preferred a non-statutory approach thus: “A Cosmetic Regulatory Guidance Note should be established by NICNAS, the ACCC and the TGA in equal partnership in consultation with stakeholders and other relevant regulators to clarify the distinction between cosmetic and therapeutic products”.
Australian Self-Medication Industry [ASMI]	Agrees but advises that legislation may only be useful if the document is used to indicate where therapeutic claims start, rather than having legislation that defines what a cosmetic claim is. Consumer involvement was also recommended.
Australian Society of Cosmetic Chemists [ASCC]	Agrees but any policing should be the responsibility of the ACCC.
Colgate-Palmolive	Guidelines to be issued by a partnership of industry and regulators (ACCC, NICNAS and TGA)
Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd	Agrees with the substance of the recommendation but that the ACCC should be the lead agency. An update mechanism should be built in to the guidelines in the manner of the Canadian Claims Guidelines.
Direct Selling Association of Aust Inc [DSAA]	Agrees with the general thrust of ACCORD and CTFAA.
Direct Selling Association of NZ Inc	Does not agree that cosmetics should be regulated by an agency that regulates therapeutic products.
Employers & Manufacturers Assoc (N) Inc [EMA]	Does not agree that cosmetics should be regulated by an agency that regulates therapeutic products.
Pavlidis, Dr C	Agrees.
Wellada (NZ) Ltd	Cosmetic claims should be allowed for sunscreens.

RECOMMENDATION 2 – ANTIPERSPIRANTS

Antiperspirants 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.

RESPONDENT	RESPONSE
<p>ACCORD, and supported by: *Amway of Aust Ltd *Beiersdorf Aust Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd</p>	<p>Agrees with the first sentence of the recommendation but does not agree that other antiperspirant agents should be treated as Class II medicines.</p> <p>Unilever points to onerous, costly and restrictive Australian requirements.</p>
<p>Australian Aluminium Council [AAC]</p>	<p>The Council did not comment on the recommendation. It was anxious that a media reference about a rumoured link between antiperspirants and breast cancer should be qualified that there was no evidence to support such a link. The Council also requested that the Medicines Evaluation Committee's commentary on a FDA warning statement be supported by a statement that "acknowledges that the dermal intake of aluminium is so low as to be almost negligible as a source of entry and, as such, is not a problem for healthy people and the majority of those unfortunate enough to be in ill health".</p>
<p>Australian Competition & Consumer Commission [ACCC]</p>	<p>Does not raise any issue for the ACCC.</p>
<p>Australian Self-Medication Industry [ASMI]</p>	<p>Agrees with first sentence of the recommendation but believes that new ingredients of comparable risk profile should be excluded from regulation. "At the very least such actives should be considered for acceptability in Class I medicines".</p>
<p>Australian Society of Cosmetic Chemists [ASCC]</p>	<p>Agrees. The ASCC further recommends that these excluded goods should be regulated as cosmetics with regards to labelling, claims (provided that comply with the definitions and guidelines of cosmetics) and excipients. This would satisfy the principles of 1, 4, 5 and 6.</p>
<p>Colgate-Palmolive</p>	<p>Agrees with the recommendation in principle "but is concerned that new product innovations should not default to Class II medicines simply because they do not contain one of the historical, listed ingredients". Favours topical antiperspirants not being treated as therapeutic products if the ingredients are listed on the ACIS, and the products not included in any schedule to the SUSDP.</p>

Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd	Agrees.
Cosmetic, Toiletry, Fragrances Association (NZ) [CTFANZ]	Agrees.
Direct Selling Association of Aust Inc [DSAA]	Agrees with the general thrust of ACCORD and CTFAA.
Direct Selling Association of Australia [DSA]	Agrees.
Pavlidis, Dr C	Agrees.
Anonymous company1	Agrees.

RECOMMENDATION 3 – ANTIDANDRUFF PREPARATIONS

Antidandruff shampoos, hairdressings and 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.

RESPONDENT	RESPONSE
<p>ACCORD, and supported by: *Amway of Aust Pty Ltd *Beiersdorf Aust Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd</p>	<p>Does not agree. Believes that these products should be Excluded Goods but with improved ingredient control and consumer product information in both countries.</p> <p>Unilever points to onerous, costly and restrictive Australian requirements.</p>
<p>Australian Self-Medication Industry [ASMI]</p>	<p>Some members favoured these products to be Excluded, consistent with the EU. Other members who market <i>scheduled</i> products believe that the expectation of efficacy for what they regard as a therapeutic action, regardless of consumer perception, should ensure <i>unscheduled</i> products are retained under some level of control by the Joint Agency.</p>
<p>Australian Society of Cosmetic Chemists [ASCC]</p>	<p>Agrees and further recommends that:</p> <ul style="list-style-type: none"> (i) excipients be used from ingredients that are currently on the ARTG or AICS; (ii) new excipients be regulated by NICNAS; and (iii) cosmetic labelling be used except for quantifying and naming the actives in the exempt products.
<p>Colgate-Palmolive</p>	<p>Does not agree because it does not seem to be in accord with guiding principles 1 and 2. Understands that if the products were Excluded Goods, their labelling would have to meet the labelling requirements of the <i>Trade Practices Act 1974</i>.</p>
<p>Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd</p>	<p>Acceptable to continue classifying these products as Exempt, but there is uncertainty about such a classification continuing under the Joint Agency. CTFAA also states that because these are low risk products and because consumers regard dandruff as evidence of uncleanliness rather than as a medical condition, the products (particularly pyrithione zinc and piroctone olamine) should be Excluded. The exempt category does not address the assessment of ingredient safety issues or the need for full ingredient labelling. CTFAA also points out the high cost of \$NZ5000 to have these products classified as “related products” under the <i>Medicines Act 1981</i>.</p>

Cosmetic, Toiletry, Fragrances Association (NZ) [CTFANZ]	Does not agree that these products should be treated as exempt therapeutic products. Supports discontinuing them as “related products” under the <i>Medicines Act</i> 1981. Favours their being treated as a sub-set of the HSNO Cosmetic Code.
Direct Selling Association of Aust Inc [DSAA]	Does not agree. Follows ACCORD and CTFAA.
Pavlidis, Dr C	Agrees.
Pharmaceutical Society of Australia [PSA]	Agrees with the first sentence but has reservations about those unscheduled products being exempted from the licensing and manufacturing controls – ketoconazole being cited as an example.
Anonymous company1	Agrees.

RECOMMENDATION 4A – PRIMARY SUNSCREENS

Primary sunscreens where SPF>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 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 (both “mandatory” and “optional”) are expressed in the manner prescribed by AS/NZ 2604:1998 and no other.

RESPONDENT	RESPONSE
ACCORD, and supported by: *Amway of Aust Pty Ltd *Beiersdorf Aust Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd	Noted and recommends that the Joint Agency and/or relevant regulator adopts the international SPF standards currently accepted by the EU, USA and other comparable countries in addition to the AS/NZS.
Australasian College of Dermatologists	Agrees.
Australian Self-Medication Industry [ASMI]	A majority of the membership agrees.
Australian Society of Cosmetic Chemists [ASCC]	Agrees but sought clarification of the word “acceptable” in “acceptable international standard”.
Colgate-Palmolive	Agrees and recommends that the AS/NZS standard should be included in the relevant regulations made under the <i>Trade Practices Act 1974</i> .
Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd	Accepts the present arrangements but points out that a cosmetic classification as in New Zealand and the EU could be justified. Strongly supports the recommendation that the Joint Agency moves to recognising international standards for testing of sunscreens. A single world standard appears to be some years away and deferral to await such a standard is unwarranted.

Cosmetic, Toiletry, Fragrances Association (NZ) [CTFANZ]	Does not agree. There is excessive regulation. Recommends that the AS/NZS be revised to accept international static SPF if a single international standard is developed. Such a standard should be in trade practices/HSNO regimes. Excipients should be removed from the assessment process.
Direct Selling Association of Aust Inc [DSAA]	Follows ACCORD and CTFAA.
New Zealand Self Medication Industry Assoc Inc [NZSMI]	There were differing views within the Association.
Pavlidis, Dr C	Agrees.
Anonymous company1	Agrees.
Welada (NZ) Ltd	If there is to be product licensing, excipients should be excluded from the licensing requirement. There should be a cosmetic GMP as used in Switzerland.

RECOMMENDATION 4B – PRIMARY SUNSCREENS WHERE THE SPF<4

Primary sunscreens where the SPF<4 should not be classified as therapeutic products.

RESPONDENT	RESPONSE
<p>ACCORD, and supported by: *Amway of Aust Pty Ltd *Beiersdorf Aust Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd</p>	Agrees.
Australasian College of Dermatologists	Does not agree. SPF<4 should be treated the same way as SPF>4.
Australian Self-Medication Industry [ASMI]	A majority of the membership agrees but that the SPF should be disclosed and the products comply with the AS/NZS.
Australian Society of Cosmetic Chemists [ASCC]	Agrees, subject to the SPF not being displayed.
Colgate-Palmolive	Agrees and recommends that the AS/NZS standard should be included in the relevant regulations made under the <i>Trade Practices Act 1974</i>
<p>Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Beiersdorf Aust Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd</p>	Agrees but query why SPF<4 was selected.
Cosmetic, Toiletry, Fragrances Association (NZ)	This category would disappear if the CTFANZ's submission were adopted.
Direct Selling Association of Aust Inc [DSAA]	Agrees in support of ACCORD and CTFAA.
Pavlidis, Dr C	Agrees.
Anonymous company1	Agrees.

RECOMMENDATION 4C – MOISTURISERS WITH A SECONDARY SUNSCREEN

Moisturisers that contain a sunscreen as and for a secondary purpose where the SPF \geq 4 should not be classified as therapeutic products, subject to conditions. (Note: see the draft report for the list of conditions).

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.

RESPONDENT	RESPONSE
<p>ACCORD, and supported by:</p> <ul style="list-style-type: none"> *Amway of Aust Pty Ltd *Beiersdorf Aust Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company² *Unilever Australia Ltd 	<p>Agrees but notes that some members supported the status quo because the changes would affect Australian manufacturing and adversely affect the poor return on the already high investment. Some members thought that labelling standards in AS/NZS could be added to the conditions. ACCORD recommends that the Joint Agency and/or relevant regulator adopts the international SPF standards currently accepted by the EU, USA and other comparable countries in addition to the AS/NZS. Amway raised the high costs of excipient evaluation by TGA. Beiersdorf adds that the range should be regulated by NICNAS. Present arrangements have prevented the introduction of new secondary sunscreens. P&G raised the high GMP compliance costs. Unilever points to onerous, restrictive and costly barriers to trade and to delays.</p>
Australasian College of Dermatologists	Does not agree.
Australian Competition & Consumer Commission [ACCC]	Concerned about enforcement issues; points out the limits of ss.52 and 53 of the <i>Trade Practices Act 1974</i> . Notes that it is unusual for a product formerly regulated by a specialist agency to be picked up by a general consumer protection agency if concerns remain.
Australian Consumers' Association [ACA]	Does not agree.
Australian Health Industry Inc [AHI]	Does not agree.
Australian Self-Medication Industry [ASMI]	The majority do not agree with the recommendation. A minority favoured it in order to ease imports from Europe.
Australian Society of Cosmetic Chemists [ASCC]	Does not agree and favours the status quo and further, does not support the display of the SPF on non-therapeutic moisturisers. The ASCC wants "changes to be made to facilitate the current therapeutic good processes for sunscreens".

Cancer Council (The)	Does not agree.
Cancer Society of New Zealand Inc	Does not agree because all products with a SPF are therapeutic, lack of regulation will allow for misuse and changes would be detrimental to the confidence of the public in sunscreens as a whole.
Colgate–Palmolive	Agrees and recommends that the AS/NZS standard should be included in the relevant regulations made under the <i>Trade Practices Act 1974</i>
Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd	Agrees, noting that SPF 20 is a realistic but arbitrary compromise cut-off. The maximum pack size was queried, especially in relation intensive care body lotions sold for use on dry legs. With reference to condition (j), CTFA states: “Cosmetics make a number of cosmetic performance claims including those blocking free radicals through the use of antioxidants. If the wording in the Review specifically relates to sunscreen protection claims and no other claims it should be so stated and this will remove our concern”. Coty refers to the AUST L system as being onerous and expensive. Australian customers are denied European products.
Cosmetic, Toiletry, Fragrances Association (NZ) [CTFANZ]	Agrees but does not go far enough in respect of the SPF 20 cut-off.
Dermatologists (41) in practice (3 with institutional affiliation)	Do not agree.
Direct Selling Association of Aust Inc [DSAA]	Agrees and supports ACCORD and CTFAA.
Ego Pharmaceuticals Pty Ltd	Disagrees. Opposed to ACCC and TGA both regulating products containing sunscreens. Concerned about low quality products from 3 rd world countries.
Federation of Australian Scientific & Technological Societies [FASTS]	Does not agree. Unapproved agents anywhere in the world could manufacture moisturisers with sunscreens without manufacturing regulations and regulated quality control.
New Zealand Dermatological Society Inc	Does not agree that the range should be outside the control of the ARTG.
New Zealand Self Medication Industry Assoc Inc [NZSMI]	There were conflicting views within the membership. Possibility of confusion in the minds of consumers.

Pavlidis, Dr C	Agrees.
Pharmaceutical Society of Australia	Does not agree. Selection of SPF is arbitrary. Consumers would not necessarily equate the presence of a sunscreen as being of a secondary purpose. Disparity of standards.
Pharmacy Guild of Australia	Does not agree and favours continuing TGA regulation.
Queensland Cancer Fund	Does not agree with deregulating because of confusing consumers and causing a lack of confidence.
Queensland Cosmetics Laboratories	Agrees but critical of certain arguments in the draft.
Ross Cosmetics Aust Pty Ltd	Does not agree because it would undermine one of the guiding principles for reform. Queried the cut-off of SPF 20.
Sigma Co Ltd	Disagrees. Favours TGA as the regulator and that all sunscreens be Listed Goods
Skin & Cancer Foundation Aust.	Does not agree, asserting that sunscreens with SPF<20 would no longer be regulated.
Standards Australia	Does not agree. Consumers will be misled.

RECOMMENDATION 5 – ANTIBACTERIAL SKIN WASHES

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

The Joint Agency, in consultation 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.

RESPONDENT	RESPONSE
ACCORD, and supported by: *Amway of Aust Pty Ltd *Beiersdorf Aust Ltd *Colgate–Palmolive *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd	Does not agree with the first part of the recommendation and proposes a stratified model based on the conditions and settings of the use of the product. Agrees with the formation of a review committee to further explore this issue and to make recommendations. [Note: in favouring the review committee, ACCORD referred only to the issue of resistance.] Colgate-Palmolive did not agree with either part of the recommendation.
Australian Health Industry Inc [AHI]	Agrees subject to the clarification that inclusion of an anti-bacterial agent does not of itself classify the goods as Class II medicines.
Australian Self-Medication Industry [ASMI]	ASMI alludes to a stratified model. Does not favour any process that replicates the NICNAS work on triclosan and quoted a EU finding that expressed no concern over the use of triclosan up to 0.3%. ASMI opposes any reform that saw complementary-based products being Class II.
Australian Society of Cosmetic Chemists [ASCC]	Agrees and further recommends that common and non-scheduled actives with low to medium level claims be reclassified Class I products.

Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd	Does not agree. Favours a stratified model with domestic products being Excluded Products; those for commercial/occupational use as Class I medicines and those for hospital and surgical use as Class II medicines. Does not agree that the subject should be reviewed.
Cosmetic, Toiletry, Fragrances Association (NZ) [CTFANZ]	Does not agree and favours these products as cosmetics.
Direct Selling Association of Aust Inc [DSAA]	Does not agree. Supports ACCORD and CTFAA.
New Zealand Self-Medication Industry Inc [NZSMI]	No consensus among members but believes that Class II is excessive.
Pavlidis, Dr C	Agrees.
Anonymous company1	Does not agree with the first part of the recommendation in the absence of definitive evidence from part B.
Anonymous company3	Does not agree. Costs are a major issue.

**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.

RESPONDENT	RESPONSE
<p>ACCORD, and supported by: *Amway of Aust Pty Ltd *Beiersdorf Aust Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd</p>	<p>Does not agree. Favours treating the range as Excluded Products if they do not contain scheduled substances and as Class I medicines if they contain scheduled substances.</p>
<p>Australian Self-Medication Industry [ASMI]</p>	<p>Does not agree and favours a stratified model. In particular, “wash on–wash off” products should not be Class II. Products with simple antibacterial claims could be exempt or excluded products.</p>
<p>Australian Society of Cosmetic Chemists [ASCC]</p>	<p>Does not agree and favours a three-tier model thus:</p> <ol style="list-style-type: none"> 1. Non–scheduled or commonly used actives with cosmetic claims to be cosmetics. 2. Non–scheduled or commonly used actives with general or medium level therapeutic claims to be Class I medicines. 3. Scheduled and/or high level claims to be Class II medicines.
<p>Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd</p>	<p>Does not agree and favours these products as cosmetics.</p>
<p>Cosmetic, Toiletry, Fragrances Association (NZ) [CTFANZ]</p>	<p>Does not agree and favours these products as cosmetics.</p>
<p>Direct Selling Association of Aust Inc [DSAA]</p>	<p>Does not agree and supports the ACCORD and CTFFA position.</p>
<p>Pavlidis, Dr C</p>	<p>Agrees.</p>
<p>Anonymous company3</p>	<p>Does not agree.</p>

RECOMMENDATION 7A – DESENSITISING TOOTHPASTES AND GELS

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

RESPONDENT	RESPONSE
<p>ACCORD, and supported by: *Amway of Aust Pty Ltd *Beiersdorf Aust Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd</p>	Does not agree. Favoured treating products as Excluded Products.
Australian Self-Medication Industry [ASMI]	Does not agree and favoured a Class I medicine classification.
Australian Society of Cosmetic Chemists [ASCC]	Agrees.
Colgate-Palmolive	Disagrees. Proposes that desensitising toothpastes containing actives that are accepted as desensitising agents for self-application by the FDA or the EU, and which are included in the ACIS should not be classified as therapeutic products.
<p>Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd</p>	Does not agree. Favoured treating products as Excluded Products.
Cosmetic, Toiletry, Fragrances Association (NZ) [CTFANZ]	Does not agree. Should be classed as cosmetics.
Direct Selling Association of Aust Inc [DSAA]	Does not agree. Follows ACCORD and CTFAA.
Pavlidis, Dr C	Agrees.

RECOMMENDATION 7B – TOOTHPASTES AND GELS 1000 mg/kg or less F⁻

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 and preventing or removing plaque should not be classified as therapeutic products.

RESPONDENT	RESPONSE
ACCORD, and supported by: *Amway of Aust Pty Ltd *Beiersdorf Aust Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd	Agrees.
Australian Self-Medication Industry [ASMI]	Agrees.
Australian Society of Cosmetic Chemists [ASCC]	Agrees.
Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd	Agrees.
Cosmetic, Toiletry, Fragrances Association (NZ) [CTFANZ]	Agrees.
Direct Selling Association of Aust Inc [DSAA]	Agrees.
Pavlidis, Dr C	Agrees.

RECOMMENDATION 7C – MOUTHWASHES CONTAINING AN ANTIBACTERIAL

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.

RESPONDENT	RESPONSE
<p>ACCORD, and supported by: *Amway of Aust Pty Ltd *Beiersdorf Aust Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd</p>	<p>Agrees in principle but proposes the recommendation be revised to read: “Toothpastes and gels that contain 1000 mg/kg or less of fluoride ion and that contain an antibacterial substance for freshening breath or fighting plaque and where no therapeutic claims are made for the antibacterial substance should not be classified as therapeutic products”.</p>
<p>Australian Self-Medication Industry [ASMI]</p>	<p>Agrees.</p>
<p>Australian Society of Cosmetic Chemists [ASCC]</p>	<p>Agrees.</p>
<p>Colgate-Palmolive</p>	<p>Favours expanding the recommendation to state that “Oral hygiene products (including toothpastes that contain 1000 mg/kg or less of fluoride ion) that contain an antibacterial substance for freshening the breath or for fighting plaque and where no therapeutic claims are made for the antibacterial substance, should not be classified as therapeutic products”.</p>
<p>Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd</p>	<p>Agrees.</p>
<p>Direct Selling Association of Aust Inc [DSAA]</p>	<p>Agrees.</p>
<p>Pavlidis, Dr C</p>	<p>Agrees.</p>

RECOMMENDATION 7D – MOUTHWASHES THAT CONTAIN 220 mg/L OR LESS OF FLUORIDE ION

Mouthwashes that contain 220 mg/L 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.

RESPONDENT	RESPONSE
ACCORD, and supported by: *Amway of Aust Pty Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd	Agrees.
Australian Self-Medication Industry [ASMI]	Agrees.
Australian Society of Cosmetic Chemists [ASCC]	Agrees.
Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd	Agrees.
Cosmetic, Toiletry, Fragrances Association (NZ) [CTFANZ]	Agrees.
Direct Selling Association of Aust Inc [DSAA]	Agrees.
Pavlidis, Dr C	Agrees.

RECOMMENDATION 8 – OTHER PRODUCTS

Personal lubricants should be classified as therapeutic products, irrespective any representations that are or are not made. (Note: some respondents referred to bar soaps and blemish sticks)

RESPONDENT	RESPONSE
ACCORD, and supported by: *Amway of Aust Pty Ltd *Procter & Gamble Aust Pty Ltd *Anonymous company2 *Unilever Australia Ltd	Does not agree. Favours treating these products as Excluded Products provided there are no therapeutic claims.
Australian Self-Medication Industry [ASMI]	Further review may be indicated. ASMI points out that non-water based lubricants such as Vaseline are not regulated as therapeutic products.
Australian Society of Cosmetic Chemists [ASCC]	Agrees.
Cosmetic, Toiletry, Fragrances Association (Aust) [CTFAA], and supported by: *Avon Products Pty Ltd *Beiersdorf Aust Ltd *Coty Aust Pty Ltd *Pax Aust Pty Ltd *The Heat Group Pty Ltd	Does not agree. Internal use products of this kind should be classed as medical devices but when for external use as cosmetics.
Direct Selling Association of Aust Inc [DSAA]	Does not agree and supports the ACCORD and CTFAA positions.
Pavlidis, Dr C	Agrees.
Anonymous company1	Agrees but points out that regulation of these products in the past appears to have been largely unsuccessful.