

Response to Review of the regulation of products at the interface between cosmetics and therapeutic goods

Thank you for the opportunity to respond to this document. Where ever possible responses are provided in the same order as the corresponding comments presented within the review document.

It was noted, disappointingly, that some statements made in the document were erroneous. Some of these errors may be contextual but on occasion manage convey that the cosmetic manufacturing industry is in disarray because it is not stringently regulated.

These statements, particularly *Page vi paragraph 5 (Summary) The absence of basic sanitary controls on cosmetic manufacturing premises in Australia is noted.* Are strongly refuted. "The statement possibly should mean the absence of mandated sanitary controls....."

It was further noted that simplification of circumstances described more fully later in the document, provides erroneous conclusions in table one. For example both "Antibacterial skin washes" and "Anti-acne skin cleansers" may be either Registered OR Listed, depending on the active ingredients and the claims made.

1. INTRODUCTION

Page 14, paragraph 8, describes the demographics of cosmetic products purchasing. It highlights that collectively, approximately 95% of cosmetics are purchased through major supermarkets, pharmacies, cosmetic retailers and/or department stores. This in itself indicates that the vast majority of cosmetics are purchased through established supply chains.

Page 15, paragraph 4, states (erroneously) that "*A detailed evaluation of final productoccurs with only a few of the classes of products that are the subject of this report*", More correctly this statement could read.... "*A detailed evaluation of final productoccurs at regulatory level, with only a few of the classes of products that are the subject of this report*".

Page 19, paragraph 3, interestingly appears to forecast an unstable game of catch up, in stating the intent to engage in regular consultation and updating of guidelines. Perhaps more appropriately, the agency should undertake to adopt series of guidelines are reviewed at predetermined intervals, and that these reviews will include consultation with stakeholders. An approach of this nature will allow product development to take place within a known environment.

** the following comment is an adjunct and not directly related to the review process**

p20, paragraph 1: *Cosmetic science is expanding and the trend to cosmeceuticals will present future difficulties for regulators and the industry.* More of a concern to the regulators and industry should be the distinct and significant lack of educational and training opportunities available in cosmetic science within Australia. To the author's knowledge there is at present only one tertiary institution offering any sort of qualifications in this field. Those few individuals who do hold formal qualifications in this field have generally gained them through international distance education.

2. Overview

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Page 25, paragraph 5, describes *The Manufacture of Cosmetic Products*, and indicates that manufacturers range from prestigious international cosmetic houses to those service two dollar shops and craft -markets.

- This appears to be a significant extension from the previously stated purchasing demographics, which indicate that 95% of cosmetics are purchased through large, mainstream outlets.
- Unfortunately these descriptives also pertain to the retail outlets rather than the manufacturing facilities themselves. Whilst not specifically suggested, it is inferred that smaller businesses are to some degree lacking in manufacturing credos.

Unfounded assumptions are better left outside the scope of credible documents.

Missing also from this overview is the significantly discerning nature of the Australian consumer. Specific, particularly to this industry, is the absence of 'needs' criteria coupled uniquely with a very high consumer demand. Cosmetics are predominantly 'wants', being for the main part 'luxury' items. This means that the consumer is particularly discerning and products that do not meet the expectations of the client are not the subjects of repeat purchase. This places significant pressure on even 'two-dollar shop' items to meet fundamental quality standards.

Failure to attract and maintain regular clientele by its very nature excludes low quality players very quickly.

It is perhaps this characteristic which most significantly differentiates, *in the consumers mind*, cosmetics from therapeutics. Therapeutics are purchased for need, and cosmetics for want.

Page 26, paragraph 2. I am left virtually speechless at the ludicrous of the statement "The ingredients of Listed Goods are assessed as safe but there is no evaluation of the efficacy or pharmaceutical stability of the finished products."

Statements such as this are defamatory not only to the sponsors of listed products who have signed statutory declarations stating that they have met the conditions required. It also fails to acknowledge the work of many fine regulators and auditors employed by the TGA who regularly and routinely assess compliance with the kinds and levels of evidence required to support therapeutic claims and that stability data held by manufactures. This statement should be corrected. Perhaps with the statement "*The ingredients of Listed Goods are assessed as safe by the regulators. The evaluation of the efficacy and pharmaceutical stability of the finished product is assessed and certified by the sponsor.*"

GENERAL COMMENT

Whilst the terms of reference look only a distinct retail market segments, fundamental risk management processes appear not to have been considered. If the author was to consider public health as the predominant risk criteria for these circumstances, the following criteria may apply:

- Chemistry of the product (Criticality of formulation)
- Number of units consumed p/a per head of population
- Leave on or Rinse off product
- Dosage form
- Discrete dosage volume
- Demographic of users – age, health, etc

In addition to the nominated pharmacological and physiological (or otherwise) action of the product.

Inclusion of these criteria would perhaps rank the designated products as follows (1 being high, 5 being low)

	Antiperspirant	Anti dandruff	Sunscreens	Antibacterial Skin Wash*	Anti Acne Washes	Toothpastes etc	Lubrican
Chemistry	2	4	2	3	3	3	2
# / units pop ⁿ	1	5	2	5	4	1	4
Leave on/	2	4	2	4	2	2	4

rinse off							
Dosage form	3	5	3	4	4	2	1
Discrete dosage volume	3	5	1	4	4	4	1
Demographics	3	3	1	5	4	2	2
Total	14	26	11	25	21	14	14

**When interpreted for household use.*

This interpretation, whilst subjective determines that

- Sunscreen's have the highest intrinsic risk in terms of performance failure, with
- Antiperspirants and Toothpastes – mostly due to their very high usage rate, and personal lubricants being of the next highest risk.
- Anti acne washes, antibacterial skin wash and finally anti dandruff products were of lower potential risk.

4.1 ANTIPERSPIRANTS

I agree with Recommendation 2.

4.2 ANTIDANDRUFF TREATMENTS

I agree with Recommendation 3.

4.3 SUNSCREEN AGENTS.

Detracting again from the credibility of the document is

- the juxta positioning of items 5 – ingredients disclosure, in the table on page 61.
- The specification alone of the feminine pronoun on page 63
- Failure to acknowledge the role the TGACC could play in remedying the situation described in the final paragraph on page 64.
- The assumption that 'back yard' manufacturers could establish any discernible presence in the market without drawing the attention of larger competitors and (thus) the ACCC.
- The assumption that the NICNAS LRCC project was successfully introduced to the Australian manufacturing environment, whilst Sydney and Melbourne may have been adequately informed, it is suggested that the 'scores' of manufacturer's found within the 'yellow pages' will be largely unaware of these circumstances.
- That failure to acknowledge the inverse argument; that primary sunscreen's may also have additional marketable benefits or equally valid cosmetic claims.
- The specification that secondary sunscreen's have a reasonable cut off weight for retail distribution of 300g or mL.

I do however agree with recommendation 4.

4.4 ANTIBACTERIAL HAND WASHES

Detracting from the documented discussion is

- an appropriate definition of Soap – loosely that being a product manufactured using an alkaline salt and fatty acids with or without additional agents. The terms soap is perhaps carelessly used when describing 'liquid soaps' which are more correctly liquid hand washes or liquid surfactants. Soaps, because of their alkaline characteristics do have intrinsic antibacterial properties, not often shared by un-medicated hand washes.
- The final paragraph on the page should be corrected to, Antibacterial hand washes, so described on the label, are fully evaluated by the TGA if they are submitted for registration.....
- Page 72, view one suggests in its title that the presence of anti-microbial substances can be harmful but fails to produce argument to this effect. Instead it suggests that it may be directing sales by instigating unreasonable fear of adverse consequences, a completely different set of circumstances. I would be most interested to consider a more appropriate argument for this first point of view.
- The lack of discussion pertaining to the forth point, raised on page73 appears to indicated that this view is unworthy of consideration.

Whilst personally I believe that the indiscriminate use of triclosan could have an undesirable effect on its long term efficacy, it is difficult to imagine circumstances where organisms within a household environment could mutate to become a threat to public health. Environmental concerns pertaining to proliferation of triclosan in waterways may be an altogether different argument, one not related directly to this field.

Comparative investigations have determined that there is a critical concentration of triclosan and contact time required to achieve sanitisation of hands using these washes. The majority of the 'household' antibacterial hand washes lack the combination of active ingredient concentration and instructions as to necessary usage time to merit realistic 'antibacterial' performance claims. It would appear that despite regulation, many of these products do not perform to recognised standards.

An issue not even raised in this discussion is 'dispenser' type antibacterial hand washes often used in the bathroom facilities of commercial and/or industrial premises. These solutions are of greater concern because they

- often carry 'unsubstantiated' 'antibacterial' claims and
- are usually of a design that requires them to be 'topped-up' routinely by janitorial staff.

These circumstances could potentially give rise to circumstances where by resistance could develop, large numbers of individuals exposed to 'contaminated' product and exposed individuals spread the resistant organisms over a large area.

Thus I can not agree with part A of Recommendation 5 in the absence of definitive evidence from part B.

Additionally the proposition that hand washes containing antibacterial agents (irrespective of their purpose) be regulated, appears

- not to consider the role of preservative systems in multi-use products
- not to consider the potential for re-positioning of products as antibacterial 'body' or 'skin' washes
- to limit the potential legitimate and desirable inclusion of substances which may (or may not) have antibacterial action in a product; would, for example this circumstance exclude the use of eucalyptus, lemon myrtle oil, rosemary oil and the such like which may have limited 'antibacterial' actions but have other marketable roles?

Perhaps the suggestions used in the sunscreen argument could be extended to this field? It could be noted that household packages of antibacterial hand washes are likely to:

- Be smaller than those used in commercial or medicinal environments
- Carry general germicidal - antibacterial claims rather than organism specific or antiviral, or antifungal claims
- Be intended specifically as a dermatologically pleasing substitute for bar soaps

It is thus proposed that non-specific antibacterial claims be permitted on liquid hand washes without regulation with the following provisos:

- The claim is limited to Household / Bathroom / Personal Antibacterial / Germicidal hand / skin wash.
- The pack size is less than 300mL /g.
- The closure system precludes 'topping up' and refills are not available.

4.5 ANTI ACNE PRODUCTS

This argument appears to be a direct extension of the previous;

- Can topical washes kill bacteria? and further
- Can this prevent (or reduce) acne or pimples that (may) result from bacterial infection of the skin.

Since it is acknowledged that little is known about the first set of circumstances, even less is known or demonstrable in the second. Does, for example the use of anti-bacteria washes kill 'good' as well as 'bad' bacteria?

A sensible approach would be to

- Allow moderate cleaning, managing, drying, helping, aiding etc - reduction claims as cosmetics, and
- stronger claims such as proven, treat or kill be regulated as Class I or II products, depending on the active ingredients.

This will allow the market to clearly choose between 'assistance' and 'treatment'.

4.6 TOOTHPASTES

No comments provided.

4.7 OTHER BORDERLINE PRODUCTS

PERSONAL LUBRICANTS.

Page 84, paragraph one. Personal lubricants are usually water miscible gels. There are usually no active ingredients.....(to line three) unless a claim is made for therapeutic or diagnostic purposes.

It should be noted the lubricants are routinely used in both internal and external ultrasound procedures. Whilst these items should be regulated as devices according the definitions, an investigation of the market place appears to indicate that rarely (if ever) is the product the subject of a listing.

These products are generally:

- Supplied in bulk
- Topped up into usage dispenser bottles
- Heated for patient comfort and
- Used during internal investigations.

This I agree with Recommendation 8 but point out that regulation of these products in the past, appears to have been largely unsuccessful.