



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

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

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DRAFT FOR COMMENT

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ABBREVIATIONS

ACCC	Australian Competition and Consumer Commission
ACH	Aluminium chlorohydrate
ACSPA	Australian Consumer & Specialty Products Association
Agency	Trans Tasman Agency to Regulate Therapeutic Products
AGRД Vol.2	Australian Guidelines for the Registration of Drugs, Volume 2
AICS	Australian Inventory of Chemical Substances
ARTG	Australian Register of Therapeutic Goods
ASMI	Australian Self Medication Industry
AS/NZS	Australia and New Zealand Standard (for sunscreens)
COLIPA	Comité de Liaison des Associations Européennes de L'Industrie de la Parfumerie, des Produits Cosmétiques et de Toilette. (The European Cosmetic, Toiletry and Perfumery Association)
CTFAA	The Cosmetic, Toiletry and Fragrance Association of Australia Inc
CTFANZ	The Cosmetic, Toiletry and Fragrance Association of New Zealand Inc
ERMA	Environmental Risk Management Authority (of New Zealand)
FDA	Food and Drug Administration (of the United States of America)
GMP	Good Manufacturing Practice, (Code of)
HSNO	<i>Hazardous Substances and New Organisms Act 1996</i> (New Zealand)
LRCC	Low Regulatory Concern Chemicals
MHRA	Medicines and Healthcare products Regulatory Agency (of the United Kingdom)
NCCTG	National Coordinating Committee on Therapeutic Goods
NDPSC	National Drugs and Poisons Schedule Committee
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NZSMI	New Zealand Self Medication Industry
OTC	“Over the counter” i.e. non-prescription
PBS	Pharmaceutical Benefits Scheme
RPBS	Repatriation Pharmaceutical Benefits Scheme
SPF	Sun Protection Factor
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TGA	Therapeutic Goods Administration
ZACH	Zirconium aluminium chlorohydrate
ZAG	Zirconium aluminium glycine

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Submissions

Written submissions or comments were received from, or interviews conducted with:

Australian Competition & Consumer Commission
Australian Consumer & Specialty Products Association
Australian Health Industry Inc
Australian Self Medication Industry
Cancer Council of Australia
Consumers' Health Forum of Australia
Cosmetic, Toiletry and Fragrances Association of Australia Inc
Cosmetic, Toiletry and Fragrances Association of New Zealand Inc
Direct Selling Association of New Zealand
Employers & Manufacturers Association (Northern) Inc
Environmental Risk Management Authority (of New Zealand)
Healthcare Manufacturing Group
National Industrial Chemicals Notification & Assessment Scheme
The Australian Society for Microbiology Inc
The Australian Society of Cosmetic Chemists Inc
Therapeutic Goods Administration

TERMS OF REFERENCE

1. Review the appropriateness of current legislation and guidelines in the regulation of products at the interface incorporating:
 - a) A summary of the current Australian and New Zealand regulatory frameworks (including Commonwealth and State schemes);
 - b) A summary, discussion and comparison of these regulatory frameworks with those in the USA, Canada and Europe;
 - c) Identification of any ‘grey areas’ in the current regulatory frameworks;
2. A review of the current Australian and New Zealand systems for the regulation of the following product categories to determine whether they would be most appropriately regulated as medicines through the joint regulatory scheme for therapeutic products or separately as cosmetics in Australia and New Zealand:
 - antiperspirants;
 - mass market antidandruff shampoos;
 - sunscreens (including moisturisers containing a sunscreen);
 - antibacterial skin washes;
 - antibacterial skin cleansers (anti-acne products);
 - toothpastes and mouthwashes; and
 - any other product categories that may be candidates for reform.
3. Recommendations on changes that could improve regulation at the interface for product categories listed above, including changes that could enhance the transparency and usability of regulatory documents such as the ‘Cosmetic Claims Guidelines’.
4. Consultation with stakeholders including:
 - a) The Therapeutic Goods Administration – Non-prescription Medicines Branch and NICNAS;
 - b) The Australian Competition and Consumer Commission (ACCC);
 - c) The Cosmetic, Toiletry and Fragrance Association of Australia (CTFA);
 - d) The Cosmetic, Toiletry and Fragrance Association of New Zealand;
 - e) The Australian Chemical Specialty Products Association (ACSPA);
 - f) The Australian Self-Medication Industry (ASMI);
 - g) Australian Society of Cosmetic Chemists (ASCC)
 - h) The New Zealand Self Medication Industry
 - i) Consumer’s Health Forum of Australia;
 - j) Medsafe (New Zealand);
 - k) Medicines Evaluation Committee;
 - l) Complementary Medicines Evaluation Committee
 - m) State and Territory governments;
 - n) National Coordinating Committee on Therapeutic Goods (NCCTG).

Guiding principles for reform of the regulation of products at the cosmetic-therapeutic interface

The Therapeutic Goods Administration, through its NICNAS and Non-prescription Medicines regulators, is undertaking a review of the regulation of products at the interface between cosmetics and medicines. The review was commenced in response to recommendation 5.4 of the *Final report and recommendations for NICNAS low regulatory concern chemicals (LRCC) reform initiative* (June 2003).

The outcomes of this review may include recommendations for reform of the regulation of products at the cosmetic-therapeutic interface. Where this is the case, the following principles will apply.

1. The primary consideration will be to 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 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 a 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).

SUMMARY

The purpose of this Report is to consider the controls appropriate to a range of external use products that might be regarded as being of low risk and which share characteristics of both cosmetics (or toiletries) and therapeutic products.

Low risk alone does not make something a candidate for classification as a cosmetic if its purposes are mainly and generally for therapeutic use. The *Therapeutic Goods Act* 1989 (Aus), for all its complexity, does provide a tier of controls within its framework to accommodate the many and varied products captured by the definitions of “therapeutic use” and these are generally risk-based. The *Medicines Act* 1981 (NZ) is simpler in this respect. Unlike the Australian Act, however, the NZ Act creates a class called “Related products” that covers a number of products having characteristics of both cosmetics and medicines.

The relevant parts of the Australian and New Zealand Acts are considered in detail because of the signing of a treaty between the governments of both countries to create a joint agency to regulate therapeutic products. The Report also had to provide overviews of the state of affairs in a number of other countries and these were helpful in arriving at the recommendations. Key definitions from the various jurisdictions are included as an appendix. Each of the classes of goods is then considered. There was extensive consultation with industry, government and others in both Australia and New Zealand. Many products were examined in isolation but the opportunity was also taken to see how they were presented in retail settings.

In the Introduction, the Report posed the question of “What are the goods in the market?” To assist in answering this question, the whole picture must be considered by taking into account not only composition and intended use of the goods but also presentation and marketing. The Report has been guided by a number of decisions of the courts on the analogous food and drug interface. The creation of decision tree or similar might be seen as a means of placing beyond doubt articles whose classification is not immediately obvious. The Report considers such an approach is, at best, a partial solution. Common sense and judgment play a role.

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.

Six classes of low risk products were selected for consideration following the NICNAS Reports. Within some classes, there were sub-classes. The Report was also able to consider other borderline products that came to attention during the course of the interviews.

To assist manufacturers and regulators, co-operation between industry and government in Australia has resulted in the development of guidelines to help in arriving in determining a classification. In cases of doubt, the use of guidelines should resolve most queries. To this end, the NCCTG has, for over ten years, published its *Cosmetic Claims Guidelines*. The format of the document is generally considered satisfactory but

there was agreement by all parties who were interviewed that any future guidelines should exclude Column B as it adds little and creates further uncertainty. The document itself should be issued and managed by the Joint Agency in consultation with stakeholders and other regulators, rather than by the NCCTG. If necessary, it should be underpinned in legislation.

The term “**Antiperspirants**” meets one of the definitions of “therapeutic use” within the *Therapeutic Goods Act 1989*. Antiperspirants are regulated in Australia at the lowest level, being ‘Exempt Goods’. Despite this, they behave in the market place in every way as toiletries and nothing was said against this during the interviews. Accordingly, they are considered by the Report to be predominantly toiletries even if they act physiologically. In New Zealand, they are cosmetics.

Antidandruff products (not being included in a poisons schedule) are examples of low risk products but it is difficult to regard them as other than therapeutic products. They are already regulated under the *Therapeutic Goods Act 1989* at a low level and this seems appropriate under the new Joint Agency arrangements.

Sunscreens are included in a wide range of formulations for application to the human body. Primary sunscreens are intended for important therapeutic purposes and the Report believes that the Joint Agency should so classify them. The classification of moisturisers that contain sunscreens has posed problems for many years in Australia where they have been treated as therapeutic goods or as cosmetics, depending on what is stated on the label. No such difficulty exists in New Zealand where all sunscreen products – both primary and secondary - are cosmetics. By applying the test of “what are the goods in the market?”, the Report concluded that moisturisers that incorporated a sunscreen for a secondary purpose were mainly and generally cosmetics. Concern was expressed that by using various presentations, a product that was ostensibly a moisturiser with a sunscreen was in reality a primary sunscreen and could escape the controls placed on therapeutic products. To address this problem, a number of conditions are proposed to ensure that moisturisers containing a sunscreen for secondary purposes are presented in a way that truly reflects their position in the market place.

The Australia / New Zealand Standard AS2604 classifies sunscreens with an SPF of less than 4 as “very low protection sunscreens”. These products cannot reasonably be regarded as having realistic and meaningful sun screening properties, especially when in use. Accordingly, the Report considers that these products should be regulated as cosmetics.

Antibacterial hand washes for domestic use presented a problem in classification. There is considerable controversy in the literature and in professional microbiological circles about the public health implications of their use, irrespective of the claims made on the label or in advertisements. The inclusion of antibacterial agents in domestic hand washes seems to be mainly for marketing purposes. Australia treats these products as therapeutic goods and requires a high level of evaluation. In New Zealand, there are not controlled under the *Medicines Act 1981*. For the time being, the Report believes that the Joint Agency should act cautiously and follow the Australian approach. Before any relaxation is made to the controls, the Report recommends that the whole matter be studied in detail by an expert committee or body to be determined by the Joint Agency.

Antibacterial acne washes are intended for a large and sensitive market. Teenagers should have a reasonable expectation that these products will live up to their claims and are apt for the purpose. The Report considers that if there is a representation about preventing or treating acne, the products should be controlled by the Joint Agency. Examination of particular offerings – examples of which are given – on the shelves indicated some manufacturers were pushing the boundaries by classifying their products as cosmetics.

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 while having a therapeutic purpose are of very low risk and should not be classified as therapeutic products by the Joint Agency.

Densensitising toothpastes are also of low risk and are classified as therapeutic goods. They are often recommended by dentists for prevention of a short but often painful condition, and there should be an expectation that they will have been shown to work on the basis of properly controlled trials. For this reason, the present classification should remain. The present classifications of **mouth washes** that contain antibacterial agents were uncontroversial as they merely breath fresheners and therefore cosmetic or treatments for gingivitis in which case they are for therapeutic use. Low concentration fluoride mouthwashes are recommended as being excluded from the Joint Agency's control provided therapeutic claims are not made, except those relating to plaque and dental caries.

Antiseptic hand wipes have a limited role in hygiene and because they have some features similar to antiseptic hand washes, the Report has recommended that they be considered with them.

Blemish sticks are ostensibly cosmetic products but when the composition and labelling are taken together, some brands would appear to have as their primary function the treatment for acne in which case they should be regulated as therapeutic products.

Other borderline products include **personal lubricants**. If these are prepared, packed, labelled and advertised for this purpose and this purpose alone, it is difficult to see them as therapeutic products. While most personal lubricants are captured by the provisions of the *Therapeutic Goods Act 1989*, it is possible that some are not. Because of potential contact with damaged mucous membrane, the Report recommends that all personal lubricants (irrespective of the presence or absence of purposes for use in advertisements or labels), are treated as therapeutic products by the Agency by way of a declaration to remove any doubt as to their classification.

Table 1: Summary of present Australian and New Zealand and proposed Joint Agency classifications for products at the interface of cosmetics and therapeutic products.

ITEMS	AUSTRALIA (present)	NEW ZEALAND (present)	JOINT AGENCY (proposed)	NOTES
Antiperspirants (Al, Zn, Zr)	Therapeutic good – Exempt.	Cosmetic.	Cosmetic.	
Antidandruff shampoos (unscheduled)	Therapeutic good – Exempt.	Related product.	Therapeutic product - Exempt	
Sunscreens, primary	Therapeutic good – Listed.	Cosmetic.	Therapeutic product (Class I).	Claims limited to sun screening.
Moisturisers with secondary sunscreen	Therapeutic good - Listed.* Cosmetic.	Cosmetic.	Cosmetic (subject to conditions).	If SPF disclosed or claims made.
Sunscreens with SPF<4	Therapeutic good – Exempt.	Cosmetic.	Cosmetic.	
Sunscreens for lip use or as tinted facial make-up.	Cosmetic.	Cosmetic.	Cosmetic.	
Antibacterial skin washes	Therapeutic good – Registered.* Cosmetic.	Cosmetic.	Therapeutic product (class II).	If anti-bacterial or other therapeutic claims made.
Anti-acne skin cleansers	Therapeutic good – Registered.* Cosmetic.	Medicine.* Cosmetic.	Therapeutic product (Class II).*	If claims extend beyond cleansing acne-prone skin.
Mouthwashes	Therapeutic good – Registered.* Cosmetic.**	Medicine if >100ppm F or claims for gingivitis. Related product if <100ppm F. Cosmetic.**	Therapeutic product (Class II).* Cosmetic.**	If therapeutic claims made. ** Breath freshener only.
Toothpastes, fluoride	Cosmetic.	Related product.	Cosmetic.	
Toothpastes, desensitising	Therapeutic good – Registered.	Medicine.	Therapeutic product (Class II).	
Blemish sticks	Cosmetic.	Cosmetic.	Cosmetic.	Provided no claims made about acne except covering lesions.
Personal lubricants	Therapeutic good – Exempt.	Cosmetic.*	Therapeutic product	May not be captured by present definition.

* See notes column

RECOMMENDATIONS

1. Cosmetics

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.

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.

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 from licensing; and
- (b) the premises where the product is manufactured should be exempt from licensing.

4. Sunscreens

A. Primary sunscreens where $SPF \geq 4$ 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.

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

C. Moisturisers that contain a sunscreen as and for a secondary purpose where the $SPF \geq 4$ 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.

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.

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.

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

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.

1. INTRODUCTION

Brief history of cosmetic use

Cosmetics have been used from ancient times in many civilisations for artistic, beautifying, protective, decorative, cleansing, camouflaging, and ceremonial purposes.

The earliest cosmetics were in use in Egypt in the fourth millennium BC. By the start of the Christian era, cosmetics were in wide use in the Roman Empire.

Cosmetics disappeared from much of Europe with the fall of the Roman Empire in the 5th century AD. A revival did not take place until the Middle Ages, when crusaders returning from the Middle East brought cosmetics and perfumes back from their travels. Cosmetics reappeared in Europe on a wide scale in the Renaissance, and Italy (15th-16th centuries) and France (17th century on) became the chief centres of their manufacture. At first makeup was used only by royalty, their courtiers, and the aristocracy, but by the 18th century cosmetics had come into use by nearly all social classes. During the conservative Victorian era, the open use of cosmetics was frowned upon by respectable society in the United States and Britain. French women continued to use makeup, however, and France pioneered the scientific development and manufacture of cosmetics during that time. After World War I any lingering Anglo-American prejudices against makeup were discarded and new products and techniques of manufacture, packaging, and advertising have made cosmetics available on an unprecedented scale.¹ COLIPA, the European Cosmetic, Toiletry and Perfumery Association, estimates the world wide industry has a turnover of €190 billion, with Europe accounting for €1.6 billion. About 2000 companies employ over 500,000 people in Europe.

Therapeutic goods and cosmetics

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is the Australian Government regulator for industrial chemicals including cosmetics, and operates in accordance with the *Industrial Chemicals (Notification and Assessment) Act 1989*. The *Therapeutic Goods Act 1989* administered by the Therapeutic Goods Administration (TGA), covers the regulation of therapeutic agents and devices.

Packaging and labelling of all cosmetic products is governed by the *Trade Practices Act 1974*, and the *Trade Practices (Consumer Product Information Standards)(Cosmetics) Regulations*, administered and enforced by the Australian Competition and Consumer Commission (ACCC). Australian states and territories are responsible for the sale and control of use of industrial chemicals, including cosmetics, under separate legislative arrangements.

The distinction between therapeutic goods and cosmetics is based on two factors:

- a) *Claims made about the product* –the key consideration for the classification of a product is its proposed claim(s). A claim can be a word, a sentence, a paragraph or an implication on product labels, package inserts or advertisements. The *Cosmetic Claims Guidelines* prepared by the National Coordinating Committee on Therapeutic Goods (NCCTG) provides guidance on acceptable and unacceptable

cosmetic claims. The NCCTG guidelines are available at www.tga.gov.au/docs/html/cosclaim.htm.

- b) *The composition of the product* – although the composition of a product alone does not necessarily determine its classification, it is quite possible that an ingredient, or the concentration of an ingredient, may make the product unsuitable for classification as a cosmetic. For example, where an ingredient is a scheduled substance in accordance with the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP), the resulting labelling requirements may preclude the use of the product as a cosmetic.

Reform of the control of low regulatory concern chemicals

In November 2002, the Parliamentary Secretary to the Minister for Health and Ageing announced the establishment of a task force to investigate the reform of the regulation of industrial chemicals of low regulatory risk. A final report and an implementation strategy were published in mid-2003.^{2,3} Included in the documents were references to chemicals used in cosmetic products. Of relevance to this Report were Recommendations 5.3 and 5.4 of the final NICNAS report. Recommendation 5.3 was:

To amend the definition of cosmetics currently listed in the Industrial Chemicals (Notification and Assessment) Act 1989 to that used in the Trade Practices Act 1974 thus improving consistency in the Government's regulatory approach to cosmetics.

Recommendation 5.4 dealt with the classes of products that are the subject of this Report (see Terms of Reference) with two extra classes being added later; one extended moisturisers with sunscreens to sunscreens as a whole, and the other added oral hygiene products to the list.

The Australian and New Zealand markets

The Australian cosmetics and toiletries market is a mature market and is expanding due to increased awareness of skin care and appearance. The size of the market has been estimated by local industry organisations at \$5,200 million (retail), covering about 700 million units consumed annually, with skin care products including moisturisers accounting for 34 million units. Australia accounts for about 1.2% of the world market.⁴ An American estimate values the Australian market at \$US770 million, with imports supplying 34.7%. The hair care segment is the biggest, accounting for 24% of retail sales, with the increased popularity of high priced colorants driving the growth. Increased awareness of health and environmental issues, together with a health conscious ageing population are further stimulants to growth. Sales of men's toiletries grew by 9.2% in 2001-2002 and reached a total value of \$US68 million.

Subsidiaries of foreign companies are the main suppliers. The major sources of imports are the United States (38%), France (19%), the United Kingdom (11%) and Germany (4%).

Nearly half of all cosmetics and toiletries are purchased from the major supermarkets; pharmacies and cosmetic retailers account for about 35% and department stores, about

20%. New health and beauty chains have further reduced the percentage sold by pharmacies.⁵

In New Zealand, the wholesale cosmetic market for 2003 was about \$NZ485,700,000. The hair care market (salon and private) is the biggest accounting for 33% followed by colour cosmetics 20%, and facial moisturisers/nourishers 13.5%. Suntan and sunscreens accounted for 2.5%. (Source: CTFANZ). When taking into account the populations of the two countries and that retail prices are about double the wholesale, New Zealanders spend about the same per capita as Australians on cosmetics.

What are the issues?

Safety of products, consumer protection, the extent of regulatory definition, market fairness and inconsistency between countries seem to be the main issues. The classes of products that are the subject of this Report are cosmetics in some countries while in others they are medicines or both.

In Australia, individual ingredients of cosmetics are assessed by NICNAS while those in use in medicines are assessed by the Therapeutic Goods Administration. The Therapeutic Goods Administration assessments emphasise human toxicology, whereas the NICNAS assessments also take environmental and occupational health and safety issues into account. A detailed evaluation of the final product (as opposed to any assessment of ingredients) occurs with only a few of the classes of products that are the subject of this Report.

With global markets having expanded and the principle of regulatory harmonisation having been adopted by many governments, multinational companies want to develop and sell new products around the world as quickly as possible and with minimal intervention by governments. Lindenschmidt *et al* have identified barriers to regulatory harmonisation.⁶ These are:

- nationalistic reasons where local authorities believe their system is better than others in the region;
- an over protectionist policy;
- increases in government revenues by licensing and other fees; and
- maintaining the status quo is easier.

The same authors say that the goals of harmonisation are:

- the manufacturer is responsible for the quality and safety of the product (note: there was no reference to efficacy);
- post-market surveillance is the best way to track safety;
- products should not require pre-market approval; and
- acceptance of a common definition of cosmetic (but recognising that this is unlikely).

Interestingly, the authors do not seem to think that the practice adopted in the USA (and also in Australia and Canada) of treating certain borderline products (of the kind included in Terms of Reference of this Report) as “drugs” represents an insurmountable barrier to harmonisation. In other words, it does not matter how the goods are defined

but the labelling, safety and efficacy requirements need to be the same. The benefits are said to be lower costs to consumers, higher safety assurances, a wider range of products and reduction in the time taken for them to reach the market.

Differentiating between cosmetics and medicines

Just as there is an elusive border area dividing drugs and foods, so there is a similar border dividing drugs and cosmetics, often termed “the grey area” or the products themselves as “borderline products”. Terms coined to describe some, but certainly not all of the oral and topical products within the border areas include “neutraceuticals” or “functional foods” and “cosmeceuticals” (sometimes spelt “cosmoceuticals”), respectively. Table 1 summarises the position for the classes of products that this are the subject if this Report.

The term “cosmeceutical” was coined by Albert M Kligman in the 1970s.⁷ Altman defines it as “a compound that claims and demonstrates a pharmacologic alteration of cosmetic conditions or the physiologic processes involved in them”.⁸

There are many products that share attributes of cosmetics and medicines. In most cases, there is little difficulty in deciding on the classification. To the lay person, the get up or presentation of the goods, how they are described and the advertising are most likely to be the major factors in making a decision. Professionals will also take into account the composition, the intended use of the goods, any legislative provisions (especially definitions) and the precise wording on the label. There are, however, some products whose description as a medicine or a cosmetic is not easy and a decision often involves some subjectivity. Appelbe and Wingfield have recognised that “borderline cases will inevitably occur where there is doubt as to the status of the product”.⁹

It is not the purpose of this Report to attempt to produce a definitive formula, equation, definition or decision tree that enables a regulator or a manufacturer to determine whether borderline products are medicines or cosmetics. Attempts have been made, at least for foods, but the perfect formula has remained elusive. In the end, the decision has been left, in particular cases, to the courts, which themselves have wrestled with the problem, having regard to the statutes they have had to interpret. An approach taken by some jurisdictions, such as New Zealand, has been to create an extra category to accommodate articles that are difficult to readily classify. Given these problems, it is not surprising that the countries mentioned in this Report have produced Guidelines that are longer than the relevant parts of the statutes and regulations themselves.

There have been several important cases where the courts have had to determine whether something for human consumption is a food or a drug, usually for taxation purposes.¹⁰⁻¹⁷ No corresponding English or Australian case law on the cosmetic/drug interface could be located. About 30 years ago, the Food and Drug Administration of the United States prosecuted cosmetic manufacturers for placing “misbranded” drugs on the market under the guise of cosmetics. In these cases, the question centred on whether the goods were a drug or a cosmetic; the FDA won two cases – *Sudden Change* and *Line Away* – and lost a third – *Magic Secret*. Following protracted meetings and correspondence with a major company, a fourth case – *Est’ee Lauder* – in 1989 unsuccessfully challenged the FDA’s decision to treat a product as a drug when it was marketed as a cosmetic. The court decided that because the FDA’s final position had

not been established, the action had to fail. Because of this technicality, the central issue was not determined. As a way of obviating these recurring issues, Liang and Hartman advocated that products making cosmetic claims based on physiological effects should be treated as cosmetics but be required to support any claims by properly controlled studies.¹⁸

The essential feature of the food/drug cases turned on the question of what the product is on the market at a particular point in time. In the *Ribena* case in the UK in 1969, the manufacturer asserted that the product was a drug or medicine – which did not attract a purchase tax - but the Commissioners of Inland Revenue said it was not and therefore sales of the product attracted tax. In his judgment, Ungoed-Thomas J said (at page 146): “On the evidence, including in particular that of the advertisements and sales to which I have referred, it would seem to me to flout common sense to conclude otherwise than that [Ribena] is mainly and generally at any rate on the market for, normally healthy persons; sold neither therapeutically nor prophylactically but more as a diet supplement...”.¹² But the Court of Appeal unanimously reversed the decision.¹³ In a further and final appeal, the House of Lords in a 4-1 majority upheld the trial judge’s decision.¹⁴ Lord Morris observed that the case was a difficult one and in so doing reinforced the maxim that hard cases make bad law. Twenty years later in Australia, Jenkinson J adopted the same approach in *Staminade*.¹⁵ What must be borne in mind, however, is the breadth of any statutory definitions that must be interpreted for the purposes of the case before the court. For example, the definition of “therapeutic goods” comprehends more than the words “drug” or “medicine” in a dictionary.

The tests used by the courts arising from the food/drug cases might well be applied in any cosmetic/drug case and “we must, in my opinion, look at the whole picture” (Lord Wilberforce (at page 508)).¹⁴

Australian law does not recognise intermediate classifications such as “cosmeceuticals” or borderline products, nor are therapeutic goods subject to the regulations made under the *Trade Practices Act* 1974 for labelling of cosmetic products. Similarly, foods are excluded from the definition of “therapeutic goods” under the *Therapeutic Goods Act* 1989. In the United States, a product having both cosmetic and therapeutic properties must meet all the regulatory requirements, including label content, for both drugs and cosmetics.

There is no official classification of “cosmeceuticals” in most countries, although New Zealand law provides for a category called “related products”. Japan accommodates “cosmeceuticals” by calling them “quasi-drugs”. This extra classification, however, creates a second or even more borderlines with their attendant complications. One can therefore see that something for topical use might be:

- (i) a cream to reduce inflammation, e.g. hydrocortisone cream; or
- (ii) an ointment containing essential oils in a petrolatum base “to gently soothe and relax your baby”; or
- (iii) a cosmeceutical per Kligman e.g. a hydroxyacid cream for peeling purposes; or
- (iv) a cosmetic base that contains trade-marked ingredients purporting to decrease wrinkles or have an anti-sagging property. Skincare products in this group that contain naturally-derived plant or animal extracts are called “dermaceuticals”; or

- (v) a formulation that is a cosmetic but for which a therapeutic claim is made e.g. a face wash that makes claims in relation to acne but whose composition is simply a detergent; or
- (vi) a cosmetic product *simple* e.g. an eyeliner.

In these, (i) is clearly a drug and (vi) is clearly a cosmetic but (ii), (iii), (iv) and (v) can be difficult to classify readily. Note the similar use of a sorites in *Ribena* where prescribed vitamin C tablets were a medicine, an orange was a food but liquid forms of vitamin C might elicit different answers from different people. (Lord Wilberforce at page 508).¹⁴

There have been criticisms of the present regulatory approach. Vermeer and Gilchrest observed that regulatory agencies tend to classify a product as a drug or cosmetic on whether the structure or function of the skin is modified by its use. (See Appendix 1 – Definitions). They believe that the guiding principle is the nature of the skin condition that is targeted and the present approach is archaic and unworkable. Many topically applied products can be shown to modify skin physiology; moisturisers are cited as an example even though they are treated as cosmetics around the world.¹⁹ Products are on Australian supermarket shelves that have the get up of cosmetics but contain specific active agents such as CoEnzymes Q10 plus R (as separate repair day and night creams) that are said to “visibly reduce the appearance of wrinkles”; and “enhance the skin’s own anti-ageing processes”, and assert a “proven reduction in the depth of wrinkles”. In the same range, the label on another product containing the same coenzymes states “CoEnzyme R complements the restructuring process of the skin’s upper layer resulting in firmer looking skin”. CoEnzyme Q10 is also known as ubiquinone and CoEnzyme R is also known as biotin.

Despite the arguments proposing new definitions and regulation, there was no support in Australia and New Zealand for the creation of a formal intermediate category.

Statutory definitions of “drug”, “medicine”, “therapeutic goods” vary. In Australia, the definition of “therapeutic goods” centres on “therapeutic use” (see Appendix 1). Those in paragraphs (c), (d) and (e) are not relevant to this Report; paragraph (f) might, although it was introduced as a result of adverse effects from silicone breast implants for which there was a regulatory vacuum. Paragraph (a) is the ordinary or dictionary meaning of “drug” or “medicine” against which few would argue. Paragraph (b), however, comprehends an almost infinite range of articles and it is this paragraph that captures some of those that are the subject of this Report. Fortunately, there is a remedy. Section 7 of the *Therapeutic Goods Act* 1989 enables the Secretary to the Department of Health and Ageing to declare that something is, or is not, a therapeutic good. The declaration that goods are not “therapeutic goods” is found in Orders called Excluded Goods Orders.

There is an extensive literature on the regulation of cosmetics, nearly all of which is American in origin and reflects the situation in that country. Many of the papers start from the definitions laid down in the *Food, Drug, and Cosmetic Act* of 1938 and proceed to give a history of the litigation and a discussion of the legal and regulatory aspects of cosmetic claims. Some, as above, propose new definitions of the word “cosmetic” in order to accommodate articles that are essentially cosmetic products but

which make claims that would bring them within the wider definition of “drug”; this word extends to modifying or altering a physiological process.

Difficulty in determining the classification of products for human consumption or topical use will not disappear. New products enter the market and entrepreneurs and creative advertisers will test the boundaries. Protracted and expensive court cases are to be avoided. In the UK, there is an Independent Review Panel that adjudicates on how a borderline product should be classified. The panel makes recommendations to the MHRA. The panel consists of 17 members. Nearly all cases have been on the food/medicine interface. Provided guidelines similar to those produced by the NCCTG are produced by the Joint Agency, the creation of a separate panel to determine whether something is a cosmetic or a therapeutic product is unjustified and any decision could be left to the Joint Agency. Should the matter remain unresolved, resort to the courts or administrative tribunals would have to follow.

Guidelines to succeed the NCCTG’s *Cosmetic Claims Guidelines* should be drawn up by the Joint Agency following consultation with interested parties and reflect the kinds of products sold in New Zealand and Australia. As new products are the life blood of any industry, regular consultation and updating of the guidelines is recommended. These guidelines should be managed by the Joint Agency rather than the NCCTG.

Manufacturing of cosmetics

The chapters that describe the regulatory controls over cosmetics and medicines in Australia, Canada, New Zealand, the United Kingdom/European Union and the United States note that Australia exercises the least controls over manufacturing of cosmetics. Unlike the other countries, there are no general laws about whether the premises are suitable, sanitary and adequately equipped for the purpose. In an age of deregulation, the Report does not favour a licensing system, product registration or pre-market approval of final product and indeed, they are probably unjustified. Nevertheless, there should be at least general powers of inspection at any level of government and offences created for the manufacture of contaminated cosmetics, the sale of cosmetics to the prejudice of the purchaser and for manufacturing cosmetics in premises that are dirty or filthy. Foods and drugs are so regulated. The sale of contaminated and prejudicial products may already be covered by trade practices and fair trading laws. No formal recommendations are made, however, because this Report is directed to particular classes of products rather than cosmetics as a whole.

The Report

A major feature for the drafting of the Report was the need to conduct interviews with interested parties. Also essential was an examination of products actually on the market in Australia and New Zealand. Many hours were spent in supermarkets, pharmacies, department stores and body care shops looking at the goods that are the subject of this Report. Magazines were also examined.

The approach taken was to ask: “What are the goods on the market?” The question was based on several legal cases involving the food/drug interface, as earlier described. Statutory definitions must also be considered but the definitions of “therapeutic use” or similar are usually so wide that they can capture almost anything. Conversely, the

definition of “cosmetic” is such, at least in some jurisdictions, that it might be seen as preventing some articles from being so classified on the grounds that no cosmetic can alter or modify physiology. Cosmetic science is expanding and the trend to cosmeceuticals will present future difficulties for regulators and the industry.

Table 1: Comparison of how borderline products are regulated in different countries.

	Australia	Canada	New Zealand	United Kingdom/EU	United States
Antiperspirants	Therapeutic Good	Drug	Cosmetic	Cosmetic	Drug and Cosmetic
Antidandruff Shampoos (mass market)	Therapeutic Good	Drug	Related Product	Cosmetic	Drug and Cosmetic
Moisturisers with Sunscreen	Therapeutic Good	Drug	Cosmetic	Cosmetic	Drug and Cosmetic
Antibacterial Skin Washes	Therapeutic Good	Cosmetic (antibacterial cleanser). Drug (kills germs; antiseptic).	Cosmetic	Cosmetic	Cosmetic if no antibacterial claims. Drug if antibacterial claims are made.
Medicated Skin Cleansers (for acne)	Therapeutic Good	Cosmetic (as a cleanser for acne-prone skin). Drug (treatment or control of acne).	Cosmetic	Cosmetic	Cosmetic (as a cleanser for acne-prone skin). Drug (treatment or control of acne).
Mouthwashes	Therapeutic Good or Cosmetic*	Drug or Cosmetic*	Related Product or Cosmetic depending on [F ⁻]	Cosmetic	Drug and Cosmetic*
Toothpastes (fluoride)	Therapeutic good or Cosmetic depending on [F ⁻]	Drug	Related Product	Cosmetic	Drug and Cosmetic

* Depends on the claims made for the product.

Note: The term “therapeutic good” refers to Exempt, Listed and Registered therapeutic goods, signifying a graded series of controls. Certain other goods are excluded, with or without conditions, from the operation of the *Therapeutic Goods Act 1989* by Order and are not subject to the Act in any way.

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2. OVERVIEW OF THE REGULATION OF MEDICINES AND COSMETICS IN AUSTRALIA AND NEW ZEALAND

The Trans Tasman Joint Agency to Regulate Therapeutic Products

The New Zealand and Australian governments are parties to a treaty that will bring into being an Agency that will be responsible for the regulation of “therapeutic products” in both countries. The treaty will be implemented by Acts of the two parliaments and all operational aspects will be contained in “rules” and “orders”.

The *Medicines Act 1981* (NZ) and the *Therapeutic Goods Act 1989* (Aus) are expected to be repealed and both Medsafe and the Therapeutic Goods Administration will be replaced by the Joint Agency.

The peculiarly Australian term “therapeutic goods” will be replaced by “therapeutic products” and the classifications known as Listed Goods and Registered Goods (as they relate to medicines) used in Australia will be replaced by the corresponding terms Class I and Class II medicines and will be used in both countries.

Details of the new arrangements may be found on Joint Agency’s website
www.jtaproject.com

2.1 AUSTRALIA



Cosmetics laws

An early law dealing with cosmetics appeared during World War II when the Commonwealth Government prohibited the manufacture of cosmetics, except creams, lotions and semi-liquids when prescribed by a medical practitioner. This was done as a measure to help conserve materials. The regulation was introduced in 1942 but was not in operation for very long.¹

The *Therapeutic Goods and Cosmetics Act 1972* (NSW) (now repealed) seems to have been the first piece of legislation in this country that contemplated a more comprehensive regulation of cosmetics. An examination of the Act and the regulations, however, indicates that only “prescribed” (by the regulations) cosmetics would be subject to the licensing provisions of the Act. Only one cosmetic was so prescribed, this being hexachlorophene. Similarly, and despite its title, the *Therapeutic Goods and Cosmetics Act 1986* (NT) has little to say about cosmetics. Western Australia had general provisions under the *Health Act 1911*, but these have been repealed. Other jurisdictions have hardly addressed the subject, presumably relying on more generalised laws such as those dealing with public health, consumer protection and fair trading to protect the public.

Advertising puffery appears to have been generally accepted by governments and the public in relation to claims made for cosmetics unless the claims strayed into the therapeutic arena. However, misleading or deceptive claims are general offences under the *Trade Practices Act* 1974. The test for misleading or deceptive conduct is that the claim is likely to mislead or deceive and not whether it is intended to mislead or deceive. If the target audience for the goods lacks a degree of scientific sophistication, scientific or technical terms should be avoided unless they are accompanied by a clear and accurate statement of their meaning.

Labelling of cosmetics

The first express legislative foray was the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 made under the *Trade Practices Act* 1974 (Cwth) (see Appendix 1). These regulations require suppliers of cosmetics that are imported into, or made in Australia, to disclose the contents on the label in a prescribed manner. The regulations do not apply to therapeutic goods, cosmetics for export, and free samples of cosmetic products or testers. In other words, if something is a therapeutic good, these regulations do not apply to it even if the goods concerned fall within the definition of “cosmetic product”.

Cosmetics that are made in Australia by unincorporated businesses for intrastate sale are not subject to the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 for Constitutional reasons and would only be so if the States and Territories introduced identical labelling requirements or adopted the Commonwealth regulations by reference. To date, South Australia and Queensland have adopted the Commonwealth regulations under the Trade Standards Regulations 2000 (regulation 6, Schedule 4) and the Fair Trading Regulation 2001 (regulation 8), respectively. However, if a retailer, being a corporation, subsequently supplies a cosmetic product that does not comply with the regulations, the retailer is liable under the Commonwealth law.

Assessment of ingredients used in cosmetic products

The *Industrial Chemicals (Notification and Assessment) Act* 1989 (Cwth) establishes a regime for manufacturers (in the sense of synthesisers) and importers of industrial chemicals, including those to be used in cosmetics, to notify the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) of the introduction of the chemical. NICNAS assesses that chemical and enters it on the Australian Inventory of Chemical Substances (AICS). The object of the Act (s.3) is:

“to provide for a national system of notification and assessment of industrial chemicals for the purposes of:

- a) aiding in the protection of the Australian people and the environment by finding out the risks to occupational health and safety, to public health and to the environment that could be associated with the importation, manufacture or use of the chemicals; and
- b) providing information, and making recommendations, about the chemicals to Commonwealth, State and Territory bodies with responsibilities for the regulation of industrial chemicals; and

- c) giving effect to Australia's obligations under international agreements relating to the regulation of chemicals; and
- d) collecting statistics in relation to the chemicals;

being a system under which information about the properties and effects of the chemicals is obtained from importers and manufacturers of the chemicals".

NICNAS does not carry out any evaluations of final cosmetic products as supplied to the public but includes assessment of products as part of its consideration of risk to workers, the public, and the environment from chemicals. NICNAS works closely with the ACCC and the TGA to ensure adequate compliance with regulatory standards.

Cosmetics present regulatory challenges that are different from other industrial chemicals. The regulatory requirements for "cosmetic products", however, are identical to other classes of industrial chemicals, with the following exceptions:

- <100 kg per 12-month (for cosmetic use) NICNAS exemption category, where additional safeguards are specified; and
- full ingredient disclosure on cosmetic product labels.

Manufacture of cosmetic products

Cosmetics are manufactured by a variety of businesses ranging from prestigious internationally known cosmetic houses to small businesses serving hairdressers, health and beauty and "two dollar" shops, craft markets and the like. Scores of them are listed in the Yellow Pages.

Unlike the UK/EU, Canada, New Zealand and the USA, Australia does not have any general laws that relate to unsatisfactory hygiene in places where cosmetics are manufactured. Even some therapeutic goods (Exempt Goods), such as antiperspirants and antidandruff shampoos, are not subject to any laws relating to good hygiene practices. There do not appear to be any offences if cosmetics are found to have been contaminated. Of the jurisdictions, the UK/EU have the most detailed requirements, while the others have public health type laws. There is nothing in the *Therapeutic Goods Act 1989* because cosmetics are outside its scope and State public health laws do not address the issue. Consumers adversely affected by a negligent act by the manufacturer of a faulty cosmetic may have recourse under trade practices and fair trading laws, and also at common law. The goods must also be of merchantable quality under the Goods Act or the Sale of Goods Act.

Medicines laws

Drugs, poisons and medicines are comprehensively controlled under State and Commonwealth laws.² Compared with medicines, cosmetics have been subject to minimal regulation. Those containing a poison, such as *p*-phenylene-diamine hair colorants have been regulated for many years under poisons laws as they affect licensing of manufacturers, labelling (including warning statements) and packaging.

Therapeutic goods laws

The general legislative framework adopted in the *Therapeutic Goods Act* 1989 is to require therapeutic goods (medicines, medical devices and blood products) to be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully supplied. They must be manufactured in individually licensed premises.

The ARTG is divided into two parts known as Registered Goods and Listed Goods. Registered Goods are individually evaluated for safety, quality and efficacy, often with the advice of independent expert committees. Listed Goods are mainly vitamins, minerals, herbal substances, sunscreens and a number of miscellaneous substances. The ingredients of Listed Goods are assessed as safe but there is no evaluation of the efficacy or pharmaceutical stability of the finished products. There are many exemptions and exceptions to these general requirements. If therapeutic goods are not eligible for Listing, they are subject to Registration – the default category. In addition to Registered Goods and Listed Goods, some very low risk therapeutic goods, while being captured by the statutory definitions of “therapeutic goods” and “therapeutic use”, are described as Exempt Goods in that they are exempted from the need to be entered in the ARTG or manufactured in licensed premises. Still other goods are described as Excluded Goods; these goods - unconditionally or conditionally - are totally excluded from the operation of the Act and are no longer “therapeutic goods”, by Order. The Order determines whether the goods or class of goods are or are not therapeutic goods. If the goods are excluded, the Order does not reclassify them; it simply says that they are not therapeutic goods and no more. It may well be that the goods, being no longer therapeutic goods, are captured by other statutory classifications and the subjects of this Report are cases in point. Most would be cosmetic products and must comply with the labelling regulations made under the *Trade Practices Act* 1974.

Products containing sunscreens are spread across all four categories i.e. Registered, Listed, Exempt and Excluded.

Poisons laws

Each State and Territory has had for over 100 years, acts and regulations to control the supply, use and possession of drugs and poisons. These are known by different titles in the various jurisdictions but historically and generically, may be described as poisons acts and regulations. Despite differing in structure, they are functionally equivalent. Over the past 50 or so years, there has been a shift in emphasis towards the control of drugs compared with poisons used on farms, in industry and in households. The poisons acts determine whether a drug can be supplied only on prescription, from a pharmacy only or from any retailer. They also regulate in some States, the “police” aspects such as the illicit manufacture of, and trafficking in, drugs of dependence but other States have separate Acts for this purpose.

The Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) documents the decisions of the National Drugs and Poisons Schedule Committee (NDPSC), regarding classification of drugs and poisons into Schedules for inclusion or adoption in the relevant State and Territory legislation. It also includes recommendations about other controls, such as labelling and packaging.

Borderline products

Shortly after the introduction of the *Therapeutic Goods Act* 1989 in 1991, an Order was issued under section 7 of the Act to exclude certain goods from the operation of the whole of the Act, as previously described. A new version of the Order has replaced the original. Only those goods included in the Order that are relevant to this Report are mentioned below. These are shown in Table 1.

While the goods in the Table 1 are not therapeutic goods, some Registered, Listed and Exempt goods may be perceived as toiletries or cosmetics. These are:

- a) antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium;
- b) medicated anti-acne preparations having only a cleansing action or purpose;
- c) lotions, shampoos or hairdressings for the prevention or treatment of dandruff, except those that are included in a poisons schedule;
- d) some oral hygiene products;
- e) antibacterial handwashes; and
- f) some products that contain a sunscreening agent.

The question is: “Should these kinds of goods continue to be regulated as therapeutic goods or should they be regulated as cosmetics?” If the latter is adopted, full qualitatively disclosure of content becomes mandatory but the proportion of the active agent would not have to be stated on the label as required under therapeutic goods standards.

Consistent with much of the rest of the western world, Australian regulators and industry experience difficulties with classifying products that share attributes of both therapeutic goods and of cosmetic products – commonly known as “borderline products”. Table 2 summarises the position in Australia. Many products fall both within the definitions of “therapeutic goods” and “cosmetic product”. The matter is partly resolved by the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 excluding from the labelling requirements something that is a therapeutic good. Nevertheless, an interface does exist and in an effort to resolve individual problems, the National Coordinating Committee on Therapeutic Goods (NCCTG, a committee of Commonwealth, State and New Zealand officials), with the assistance of the Cosmetic, Toiletry and Fragrance Association of Australia, produced a booklet called *Cosmetic Claims Guidelines* (“the Guidelines”). The Guidelines set out examples of how wording on labels and in advertisements, composition of the product and the context in which it is used can help decide the classification. Other countries publish similar documents.

The Guidelines base the distinction on two factors; composition and proposed use. The composition does not necessarily determine the classification but the presence or concentration of an ingredient may make a product containing it unsuitable for classification as a cosmetic. The claims made on labels, package inserts and in advertisements indicate to the consumer the proposed use of the goods. This approach is logical enough but the weighting ascribed to each of the two factors for a particular product is impossible to quantify. Perception also plays a large role in deciding on

which side of the border the product should fall. Handwashes containing an antibacterial agent are examples of the dilemma.

The Guidelines then set out a table with each of the purposes for which borderline products are used, in terms of acceptable wording for a cosmetic [Column A], unacceptable wording for a cosmetic claim (unless sufficiently modified to provide a cosmetic implication) [Column B] and unacceptable wording for a cosmetic (but not necessarily acceptable for a drug) [Column C]. Those relevant to this Report are shown as Table 3.

The NCCTG Guidelines are obtainable from the TGA's website www.tga.gov.au and clicking on "Publications". The Australian Competition & Consumer Commission publishes a helpful booklet called *Cosmetics & toiletries – ingredient labelling* which reproduces the regulations.

The need for Column B is doubtful and does not appear to add additional guidance to manufacturers. There was unanimous support from both industry and regulatory sources to delete it.

Recommendation

1. Cosmetics

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.

Table 1. Goods excluded absolutely and conditionally from the operation of the *Therapeutic Goods Act 1989*. Adapted from Therapeutic Goods (Excluded Goods) Order No. 1 of 1998 and Therapeutic Goods (Excluded Goods) Order No. 2 of 1998

<i>Goods intended for use in humans, declared not to be therapeutic goods</i>		
(a) Hair bleaches, hair dyes, hair-colorants or hair-perming preparations; (e) Dental bleaches or dental whiteners (f) Preparations that are applied topically to the nails to harden, or to deter biting of, the nails		
<i>Goods that are not therapeutic goods when used, advertised, or presented for supply in a particular way</i>		
Item No.	Goods	Conditions
1	Deodorant preparations	Use for dermal application or with therapeutic devices
2	Oral hygiene preparations or devices (including dentifrices, mouth washes, breath fresheners, brushes and flosses) that are not included in a Schedule to the Poisons Standard	If benefits claimed to result from the use of the goods are restricted to those consequential on improvements to oral hygiene or the use of fluoride for the prevention of tooth decay
4	Creams, lotions or similar products for dermal application, other than: (a) preparations intended for extemporaneous dispensing for therapeutic use; or (b) products intended to provide a barrier against infection	If the goods are used solely as, or are represented to be for use solely as, emollients, moisturisers, cleansers, or protectants against water or irritant agents
5	Soap and detergent, other than medicated soap and medicated detergent	Use for skin cleansing or hair cleansing
10	Preparations containing a sunscreening substance, if the primary purpose of the preparations is neither protection of the skin from injury from solar radiation nor another therapeutic purpose	If representations about the goods do not include: (a) a statement of a claimed sun protection factor, or (b) a description of a claimed sun protection category; or (c) a reference to another therapeutic use in respect of the goods
10A	Preparations defined in the Australia/New Zealand Standard for Sunscreen Products as secondary sunscreen preparations which are: a) Preparations for application to the lips which are tinted and unmedicated; or b) Tinted facial make-up (other than moisturisers); and which are not for any other therapeutic purpose.	If the specified use, advertisement or presentation for supply of the goods makes no claims in relation to sun protection or, if any such claims are made they relate only to a sun protection factor or equivalent category description (or both) in the Australian/New Zealand Standard AS/NZS 2604-1998; and do not include a reference to another therapeutic use in respect of the goods
11	Depilatory preparations	Use for dermal application

Table 2. Summary of how borderline substances for topical use are regulated in Australia

Product Category	Sub-Category	Regulatory Status
Antiperspirants	Actives are inorganic salts of Al, Zn or Zr	Exempt from registration or listing Exempt from manufacturing licence
	Other than as above	Registration
Anti-Dandruff Shampoos	For prevention or treatment when not classified as a poison	Exempt from registration or listing Exempt from manufacturing licence
	Pharmaceutical Benefit (Repatriation)	Registration
	For prevention or treatment when classified as a poison	Registration
Sunscreen-containing products	Moisturiser without SPF on label. No therapeutic or sunscreen claims	Excluded Good. Ingredients accepted by NICNAS Label observes Trade Practices Regs
	SPF on label; SPF<4; Sunscreen claims only	Exempt from registration or listing Compliance with ANZ Standard Exempt from manufacturing licence
	SPF on label; >4 (incl moisturisers); Sunscreen claims only	Listing. Compliance with ANZ Standard
	Pharmaceutical Benefit (Repatriation)	Registration. Compliance with ANZ Standard
	SPF on label; SPF>4; Sunscreen and other therapeutic claims	Registration. Compliance with ANZ Standard
	Lipstick or tinted lip products with sunscreen with or without SPF on label	Excluded Good. Ingredients accepted by NICNAS Label observes Trade Practices Regs
Handwashes containing an antibacterial	Reference to cleansing or removing germs only. No reference to the word “antibacterial” or killing germs	Excluded good
	Herbal active ingredients, not being in the SUSDP	Listing
	Presence of non-herbal antibacterial agent. Reference to killing germs and the word “antibacterial”	Registration
Anti-acne cleansers	Unmedicated	Exempt from registration or listing Exempt from manufacturing licence
	Herbal active ingredients, not being in the SUSDP	Listing
	Any other active ingredients	Registration
Mouth Washes	If in a poisons schedule	Registration
	Breath freshening, and/or preventing tooth decay due to fluoride and/or combating plaque only	Excluded Good
	Claims for gingivitis	Registration
Dentifrices	Cleaning teeth and/or preventing tooth decay due to fluoride and/or combating plaque only	Excluded Good
	Includes a desensitising agent	Registration

Table 3. Extract from the NCCTG Cosmetic Claims Guidelines

Subject	Column A Acceptable wording for a cosmetic	Column B Unacceptable wording for a cosmetic unless sufficiently modified to provide a cosmetic implication	Column C Unacceptable wording for a cosmetic (but not necessarily acceptable for a drug)
Comedones, acne, pimples, blackheads	* cleaner for acne-prone skin * cover (hide) comedones (acne, blemishes) * removes oil		* prevent (stop) (heal) comedones (pimples) (acne) (blemishes)
Dentifrice NB. In terms of section 7 of the <i>Therapeutic Goods Act</i> 1989, toothpastes are declared to be "not therapeutic goods" providing: 1. the product is not subject to poisons schedules; 2. it contains 1000 mg/kg or less or nil of fluoride ion; and 3. claims are restricted to oral hygiene or the use of fluoride to help prevent tooth decay.	* cleans (whitens, brightens, polishes) teeth * Removes stains * Prevent (reduce) plaque (tartar) build-up (deposit) by brushing (other mechanical means) * helps maintain healthy teeth and gums * tooth decay – fluoride protects against, reduces cavities		* any implications of effect below the gumline * references to abscess, antiseptic action, gumboil, gingivitis, inflammation of gums, mouth ulcers, periodontitis, pyorrhoea, periodontal disease, sensitivity, stomatitis, thrush
Deodorant	* absorbent that helps keep you dry * anti-odorant (deodorant) * fights bad odour * kills odour-causing bacteria		* antiperspirant * controls moisture (sweat) (perspiration)
Hair	* removes (washes) (cleans) loose dandruff (flakes) from the hair * add body to (colour) (alter shape of) hair * help make hair look thicker (fuller) * revitalise appearance (look) of hair, restore beauty (lustre) (sheen) to the hair * promote lustre	* makes your hair stronger	* control (eliminate) dandruff * dandruff (anti-dandruff) shampoo (formula) * alopecia * prevent (stop) (cure) hair loss, hair thinning (baldness) * replace thinning hair * restore hair cells * stimulate hair follicles (growth)
Mouthwash	* fight (reduce) (end) bad breath (mouth odours) * helps eliminate (kill) odour-causing bacteria (bacteria that cause bad breath)	* references to plaque or tartar (see under dentifrice)	* antiseptic (antiviral) germicide * kills pathogens (germs) (odour-causing germs) * antibacterial (antimicrobial)

Subject	Column A Acceptable wording for a cosmetic	Column B Unacceptable wording for a cosmetic unless sufficiently modified to provide a cosmetic implication	Column C Unacceptable wording for a cosmetic (but not necessarily acceptable for a drug)
Skin (cleansers and soaps)	<ul style="list-style-type: none"> * helps eliminate odour caused by bacteria * cleanse oily skin * removes top layer of dead skin * cleans all types of skin (not just oily) * cleans skin * clarify, purify 	<ul style="list-style-type: none"> * purify 	<ul style="list-style-type: none"> * antibacterial (antimicrobial) * antiseptic/disinfectant (fungicide) (germicide) (viricide) * reference to disease-causing organisms, kills pathogens * anti-blemish cream * cleans cuts (wounds) * helps control (treat) infection (jock itch)

References

1. Pharmaceutical Society of Victoria. Prohibition of Non-essential Production Order (No. 3) issued on 2 April (Victorian Chemists' Year Book p.61-2 2nd ed 1943.)
2. Dwyer P, Newgreen DB. In: *The Laws of Australia*, vol 20 – Health & Guardianship, subtitle 20.11 - Regulation of Drugs

2.2 NEW ZEALAND



Cosmetics laws

There is no New Zealand Act or regulations dedicated solely to cosmetics. Instead, the *Medicines Act 1981* defines “cosmetic” (see Appendix 1) in general terms and then provides a list of articles that are considered cosmetics and not medicines. The kinds of products specifically mentioned in the Act as cosmetics are not exclusive. The Ministry of Health’s Guide interprets the lead-in words of the definition to encompass antiperspirants, sunscreen and suntan preparations, cleansers for normal or blemished skin, moisturisers for normal, sunburnt or wind burnt skin, hair conditioners, astringents and skin toners, agents to assist in the fading of spots, pimples and blemishes, antiseptics for generalised, all-over use, on the body and not on broken skin, solutions which are bathed in to relax the body, and anti-wrinkle anti-ageing products that have a superficial cosmetic effect and not a physiological effect.

Part V of the Medicines Regulations 1984 refers in general terms to hygiene in the manufacture of cosmetics. The regulations require cleanliness of clothes and the body. Infected persons are prohibited from manufacturing cosmetics, medicines and related products. The manufacturing premises must be suitably illuminated and ventilated, kept clean, be free of contaminants and have adequate wash basins and toilets.

Warning statements must be attached to containers of prescribed hair dyes under regulation 24. Dusting powders for use on babies or on inflamed, broken or abraded skin must be free of pathogens under regulation 4.

Unlike medicines, manufacturers of cosmetics do not require ministerial consent to place a cosmetic on the market. Manufacturers are not licensed. There are no labelling requirements that require disclosure of contents on the labels of cosmetics as in Australia, the EU or the USA.

Sunscreens, both primary and secondary, are cosmetics and accordingly, do not require ministerial consent before marketing. Manufacturing licences are not required. Medsafe’s *New Zealand Regulatory Guidelines for Medicines*, volume 1, 5th edition (2001) states: “Companies are encouraged to market only sunscreens that comply with the Australian/New Zealand Standard AS/NZS 2604:1998 *Sunscreen Products – Evaluation and Classification*. Companies marketing sunscreens should have evidence to support the SPF and broad spectrum claimed. Future legislation may control sunscreens as therapeutic products”. In other words, there is voluntary compliance but there are no remedies should the Standard not be met, except under fair trading laws.

ERMA does not regulate medicines but it has the capacity to regulate hazardous cosmetics or their ingredients. This is an important difference when compared with Australia’s NICNAS. NICNAS does not register products but regulates chemical ingredients regardless of their hazardous nature. ERMA can prescribe, under the Act, label content, disclosure of components, effects, and precautionary statements for the goods as they are sold to the public.

Medicines laws

The *Medicines Act* 1981 comprehensively regulates the importation, manufacture and supply of medicines. It is modelled to some extent on the *Medicines Act* 1968 of the United Kingdom. The Act also determines whether substances in medicines will be available only on prescription or from pharmacies only. If not so classed, the medicine may be sold anywhere. This aspect of the regime resembles Australia's rather than the United Kingdom's. Drugs of addiction (Controlled Drugs) are also controlled under the *Misuse of Drugs Act* 1975 and the regulations. As well as creating offences for illicit manufacture, trafficking and supply, the regulations prescribe certain labelling for Controlled Drugs when used legitimately. Where there is an inconsistency between the *Misuse of Drugs Act* 1975 and the *Medicines Act* 1981, the former prevails.

The consent of the Minister of Health is required before a medicine may be distributed and the consent must be published in the *Gazette*. Licences to manufacture medicines are required.

There are restrictions on the content of advertisements for medicines and medical devices in relation to particular diseases and physiological states but these do not extend to cosmetics and related products.

The legislation is administered by Medsafe, the medicines and medical devices safety authority and is a business unit of the Ministry of Health.

Borderline products

As well as medicines and cosmetics, the Act provides for a classification called “related products” (see Appendix 1). Related products are those having a therapeutic use as a purpose secondary to the main use. The consent of the Minister is required before a new related product can legally be distributed. Licences to manufacture related products are not required. Evidence of observance of the Code of GMP is required for related products that are taken internally such as throat lozenges that contain an antiseptic. Manufacturers of related products for external use, such as fluoride mouthwashes, dandruff shampoos and fluoride toothpastes (containing $\leq 0.1\%$ of F), are not obliged to have evidence of GMP but Medsafe encourages them so to do.

Regulation 14 requires “related products” to be labelled with an appropriate designation and trade name; the active ingredients to be disclosed quantitatively, the product’s true nature, expiry date and batch number, a dose and its frequency, directions for use, and name and address of the manufacturer. The regulation of “Related products” is in some respects operationally close to Australia’s “Exempt Goods” category but there are considerable differences in the detail and the concept of a secondary therapeutic purpose is not part of the Australian regime.

Dietary supplements are edible substances that are presented in a controlled dosage form and are intended to supplement the intake of substances that are normally derived from food. They must not be promoted for a therapeutic purpose. If a therapeutic claim is intended to be made for a product, consent must be obtained to market it as a

medicine or as a related product. Dietary supplements are regulated under the Dietary Supplements Regulations 1985.

The Environmental Risk Management Authority is created by the *Hazardous Substances and New Organisms Act* 1996, commonly known as the HSNO Act. The Act took effect from 2 July 2001. The members of the Authority are appointed by the Minister for the Environment. The Authority is the decision-making body but ERMA New Zealand administers the Act, other than operating as an enforcement agency; it does, however, monitor enforcement that is shared by several agencies listed under section 97 of the Act. These include the Ministry of Health, the Ministry of Commerce, New Zealand Customs and the police.

The object of the Act is to protect the environment and safeguard public health by preventing or managing any harmful effects of hazardous substances or new organisms. Its main role is to make decisions on application to import, develop, or field test new organisms or to import or manufacture hazardous substances. The Authority's website provides full information on its activities. (See www.ermanz.govt.nz or www.hsno.govt.nz).

For finished goods or substances to be regulated under the Act, they must be hazardous as determined by the Regulations which in large measure are derived from the United Nations publication, *Globally Harmonized System of Classification and Labelling of Chemicals*, 2003.

3. OVERVIEW OF THE REGULATION OF MEDICINES AND COSMETICS IN OTHER COUNTRIES

3.1 CANADA



Cosmetics laws

The *Food and Drugs Act* defines the word “cosmetic” (see Appendix 1). Other provisions of the Act that relate to cosmetics are written in traditional public health terms:

- S.16. No person shall sell any cosmetic that
- has in or on it any substance that may cause injury to the health of the user when the cosmetic is used,
 - according to the directions on the label or accompanying the cosmetics, or
 - for such purposes and by such methods of use as are customary or usual therefor;
 - consists in whole or in part of any filthy or decomposed substance or of any foreign matter; or
 - was manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

S.17. Where a standard has been prescribed for a cosmetic, no person shall label, package, sell or advertise any article in such a manner that is likely to be mistaken for that cosmetic unless the article complies with the prescribed standard.

S.18. No person shall manufacture, prepare, preserve, package or store for sale any cosmetic under unsanitary conditions.

The Cosmetic Regulations are made under the *Food and Drugs Act*. The regulations do not require disclosure of content, as occurs in Australia, Europe and the United States but do require the manufacturer to notify Health Canada of the quantified composition. An amendment is being sought to the Cosmetic Regulations that would require manufacturers and distributors of cosmetic products to disclose the ingredients on the labels two years after publication in the *Canada Gazette*, Part II. This Report understands that Canada may adopt the EU definition of “cosmetic product”.

The Cosmetic Regulations set out the powers of inspectors and sampling procedures. There are specific regulations dealing with:

- a prohibition on stain-removers for the teeth whose pH is <4;
- a prohibition on eye cosmetics that contain tars;
- limitations on the inclusion of mercury compounds in cosmetics;
- a prohibition on cosmetics that contain chloroform or oestrogens;
- a prohibition on claims that would indicate that the cosmetic influences the chemistry of the skin, hair or teeth;
- a warning statement for *p*-phenylene diamine hair dyes;

- the need for mouthwashes to be in security packs;
- cosmetics supplied in pressurised containers;
- all warnings to be in English and French;
- labelling: name and address of manufacturer or distributor, name of the goods, quantity and function;
- confidential notification to the government about the composition of cosmetics; and
- authority for the government to demand information from manufacturers and importers.

Medicines laws

Non-prescription medicines are expected to comply with a monograph for a given therapeutic category and the supply of medicines that depart from the monograph would be regarded as “misbranded” and attract penalties. This approach is similar in principle to that used in the United States but there are some significant differences. All products are allocated a Drug Identification Number (DIN) but the number is not unique to formulations within a product range. As in most parts of the world, there are controls on availability of medicines but these are not relevant to the kinds of products that are the subject of this Report.

Borderline products

Canada, Australia and the United States appear to be philosophically closely, but not totally, aligned on what differentiates cosmetics from drugs; if something achieves a cosmetic objective by any alteration to a physiological function, it will be classified as a drug. Antiperspirants and sunscreens are cases in point. However, unlike Australia and the United States, Canada treats a moisturiser that contains a sunscreen as a cosmetic. Whereas American law requires a product that is both a drug and a cosmetic to be labelled in accordance with both drug and cosmetic requirements, Canada, like Australia, interprets a product as being uniquely classified. Health Canada has this to say about the cosmetic/drug distinction:

The law defines a cosmetic as a product which cleanses, improves or aids the complexion, skin, hair or teeth. A beauty product or grooming aid is usually categorized as a cosmetic, but will be legally classified as a drug if it makes any claims to modify body functions, to prevent or treat disease.

Here are some examples:

A toothpaste is a cosmetic when it cleans, whitens and brightens the teeth. It is a drug when the special ingredient is added which will prevent tooth decay. A deodorant is a cosmetic because it acts to control odour in perspiration on the skin's surface. An antiperspirant is a drug because it suppresses the flow of perspiration to the skin's surface.

Health Canada publishes a 47-page guidelines booklet called *Labelling of Cosmetics* to explain the Act and the Regulations and also other regulations, such as weights and measures, that might be relevant to manufacturers. The booklet is comprehensive. There is also a set of *Guidelines for Cosmetic Advertising and Labelling Claims* produced jointly by Health Canada, Advertising Standards Canada and the Canadian

Cosmetic, Toiletry and Fragrance Association. There are similarities between this and the Australian NCCTG Cosmetic Claims Guidelines. Both are collaborations between government and industry and both give lists of acceptable and unacceptable claims. In the Canadian document, the criteria for acceptable cosmetic claims are described as follows:

- Acceptable meaning or wording for a cosmetic (as defined in the Act and the regulations)
- Net impression taken into account
- Qualified with cosmetic claim
- Each claim must be true and verifiable
- The list is not exhaustive.

The criteria for unacceptable claims are:

- Unacceptable meaning or wording as defined the Act or the regulations
- Net impression is taken into account
- Drug claim or impression/claims for physiological effect
- The list is not exhaustive.

Acceptable and unacceptable claims are related to substrate (eg hair, skin or teeth); product (eg. oral care products, vitamins/minerals/antioxidants, deodorants); or claim type (eg. anti-ageing, healthy, nourish/replenish). The Canadian Guidelines do not have a Column B [“Unacceptable wording for a cosmetic unless sufficiently modified to provide a cosmetic implication”] that appears in the corresponding Australian Guidelines. While the general approach is very similar, there are some significant differences. Under oral care products, any reference to plaque and fluoride is unacceptable in Canada for a cosmetic product, whereas in Australia, the ability to exclude by Order a class of products enables a legislative distinction to be drawn so reducing uncertainty even in the face of a therapeutic claim being ostensibly made.

3.2 UNITED KINGDOM & THE EUROPEAN UNION



Cosmetics laws

The Cosmetic Products (Safety) Regulations 2003 made under the *Consumer Protection Act* 1981 are detailed and have been written to give effect to the directives of the European Community. The Basic Directive is 76/768/EEC of 27 July 1976, to which over 30 amendments have been made. Although there are only 15 individual regulations, most are lengthy. The bulk of the regulations are the Schedules, which are negative lists of substances; these are:

- (i) 769 substances whose use is prohibited in cosmetic products.
- (ii) 34 substances prohibited when used as a fragrance.
- (iii) 66 substances which cosmetic products must not contain except subject to the restrictions laid down.
- (iv) 62 substances which in hair dyes and colourings must not be used in cosmetic products except subject to the restrictions laid down.
- (v) 157 colouring agents which cosmetic products must not contain except subject to the restrictions laid down.
- (vi) 56 preservatives which cosmetic products must not contain except subject to the restrictions laid down.
- (vii) 27 UV filters which cosmetic products must not contain except subject to the restrictions laid down.

The regulations go on to provide for labelling (including a full list of ingredients); the appointment of an appropriately qualified “responsible person” to hold qualitative and quantitative details of the composition, microbiological data, methods of manufacture (that comply with good manufacturing practices), efficacy data (where applicable) and safety data.

Annex 1 of the Directive lists the categories of cosmetic products thus:

Anti-wrinkle products

Bath and shower preparations (salts, foams, oils, gels etc)

- cleansing products (lotions, powders, shampoos)
- conditioning products (lotions, creams oils)

Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc)

Deodorants and antiperspirants

Depilatories

Face masks (with the exception of chemical peeling products)

Hair care products:

- hair tints and bleaches
- hairdressing products (lotions, lacquers, brilliantines)
- products for waving, straightening and fixing
- setting products

Make-up powders, after-bath powders, hygienic powders etc

Perfumes, toilet waters and eau de Cologne

Products for care of the teeth and the mouth

Products for external intimate hygiene
Products for making-up and removing make-up from the face and the eyes
Products for nail care and make-up
Products for tanning without the sun
Products intended for application to the lips
Shaving products (creams, foams, lotions etc)
Skin-whitening products
Sunbathing products
Tinted bases (liquids, pastes, powders)
Toilet soaps, deodorant soaps etc

Medicines laws

The *Medicines Act* 1968 and the many regulations and orders made under it are administered by the Medicines and Healthcare products Regulatory Agency (MHRA), (formerly known as the Medicines Control Agency (MCA)). It is part of the Department of Health. The adoption of EU Directives has added further complications to an already complicated set of laws. Like New Zealand and unlike Australia, the United Kingdom legislation determines not only licensing of premises, labelling and approval to market finished product, but also the classification of medicines into those that are prescription only ("POM"), pharmacy only ("P") or for general i.e. unrestricted sale ("GSL"). Unlike Australia and New Zealand, where the default category is general sale, in the UK, the default is pharmacy only medicine. As well as the *Medicines Act* 1968, there is the *Misuse of Drugs Act* 1971 that controls drugs of addiction. Good overviews of the UK laws are found in texts by Appelbe and Wingfield and by Merrills and Fisher^{1,2}.

Borderline products

The MHRA has produced a document that states, in part:

What is a borderline product?

Most human medicines are clearly identifiable as such and are subject to EC marketing authorisation procedures. However, there are some products where it is not so easy to distinguish a medicine from, for example, cosmetics or food supplements. These are known as "borderline products".

A product which is for use only as a toilet preparation, disinfectant, food or beverage is not normally regarded as a medicinal product, and, therefore, does not require a marketing authorisation before being sold in the UK. Similarly, dietary supplements, containing such familiar substances as vitamins, amino acids or minerals, are generally subject to food safety and food labelling legislation rather than medicines control. However, should any of the above contain a pharmacologically active substance or make medicinal claims (claims to treat or prevent disease, or to interfere with the normal operation of a physiological function of the human body are regarded as medicinal). For example, a toothpaste would generally be considered as a cosmetic, but if it is marketed with claims to treat or prevent "sensitive" teeth or it contains an active ingredient known to have such an effect then it would fall within the definition of a medicinal product and be subject to medicines control. Bandages and other surgical dressings are not subject to the marketing authorisation procedures unless they are medicated and the curative effect of their medication is their primary purpose.

Difficulties in deciding whether something is a medicine or a cosmetic or a food supplement, complaints about the Agency's classification process and criticism from the European Court of Justice led to the passing of the Medicines for Human Use Amendment Regulations 2000. These provide for a systematic and transparent way of making the distinctions. The Regulations (i) require the MHRA to give reasons for its decisions; (ii) set up an Independent (Advisory) Review Panel which, on request, will consider written and oral representations against the MHRA's provisional classification determinations; (iii) create an offence for non-compliance with final MHRA decisions; and (iv) restore the burden of proof in criminal proceedings on the MHRA.

A member of the Review Panel will be recognised by his or her peers as an eminent member of their profession or calling and have a wide and recent experience of, and have shown capacity in, at least one of the following activities:

- the practice of human medicine or pharmacy.
- herbal or other branch of complementary medicine.
- nutritional therapy and food science.
- the cosmetics industry.
- public health and consumer affairs.

There are 17 members of the panel with a barrister as chairman. Examination of the panel's decisions shows that nearly all the reviews have been to do with the food supplement/medicine interface; only about one per cent were on the cosmetic/medicine interface.

References

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3.3 UNITED STATES OF AMERICA



Cosmetics laws

The *Food, Drug, and Cosmetic Act* of 1938 prohibits the sale of adulterated or misbranded cosmetics. Cosmetics are adulterated if they are injurious to health, consist of or contain anything filthy or decomposed, are packed in unsanitary conditions, if the container is contaminated, or if they contain an unsafe colour additive. Misbranding refers to false or misleading particulars on the label, including omission of the name and address of the distributor; proscribed words; omitted mandatory warnings or if the product contains a prohibited colour additive.

Cosmetics marketed in the United States, whether manufactured domestically or imported, must meet the provisions of the *Food, Drug, and Cosmetic Act*, the *Fair Packaging and Labeling Act* and the regulations published under the authority of these statutes. The regulations published by the Food and Drug Administration (FDA) are all codified in Title 21, Code of Federal Regulations (21 CFR). The regulations applicable to cosmetics are stated at 21 CFR, parts 700 to 740 (21 CFR 700 to 740). The colour additive regulations applicable to cosmetics are found at 21 CFR 73, 74 and 82. Donegan has written a history of the “government and industry partnership”.¹

The statutory definition of “cosmetic” is in Appendix 1. Included in this definition are products such as skin moisturisers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colours, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product.

The FDA is only able to regulate cosmetics after products are released to the marketplace. No cosmetic products or cosmetic ingredients are reviewed or approved by the FDA before they are sold to the public. While the FDA collects cosmetic product samples as part of its plant inspections, import inspections, and complaints of adverse reactions, it acts through the Department of Justice to remove adulterated and misbranded cosmetics from the market. The FDA is not permitted to require recalls of cosmetics but does monitor companies that conduct a product recall. If the FDA wishes to remove a cosmetic product from the market, it must first prove in a court of law that the product may be injurious to users, improperly labelled, or otherwise contravenes the law.

The FDA cannot require companies to carry out safety testing of their cosmetic products before marketing. If the safety of a cosmetic product has not been substantiated, the product's label must read: *WARNING: The safety of this product has not been determined.*

The FDA does not have the authority to require manufacturers to register their cosmetic establishments, file data on ingredients, or report cosmetic-related injuries. It maintains a voluntary data collection program and companies that wish to participate in the

program forward data to FDA. In 1998, about 35-40 per cent of cosmetic manufacturers participated in the program.²

In 1977, the USA was the first country to require the disclosure of the composition of cosmetics on the label. This arose from consumer pressure. Compulsory cosmetic labelling has since been adopted in the EU and Australia.³

Medicines laws

The Federal and State governments regulate drugs. At the federal level, the FDA administers the *Food, Drug, and Cosmetic Act*. The Act provides for the FDA to determine whether a drug may be supplied only on prescription. If not, the drug may be supplied anywhere – there are no pharmacy-only medicines, unlike the rest of the western world. All prescription drugs undergo a rigorous evaluation. There is no product-by product evaluation and no registration of non-prescription (OTC) medicines. Instead, the FDA has a detailed set of monographs or rules that set out what active ingredients may be included in the 20 or so completed therapeutic classes of OTC drugs, allowable combinations (if any), doses or concentrations, pack size, and labelling, including description, permissible claims, directions for use, and any cautionary or warning statements. If an OTC drug does not meet the requirements of the appropriate final rule, it is considered “misbranded” and a "new drug." A "new drug" must have an approved New Drug Application (NDA) before it may be introduced into interstate commerce. In addition, drug manufacturers must comply with Good Manufacturing Practice regulations.

The Report understands that States can and do impose further laws to control medicines as long as they are in addition to the Federal laws.

The monograph arrangements began in 1974 and are still unfinished.

Borderline products

The FDA produces extensive and helpful information on its website about the distinctions between cosmetics and drugs. Greff, and Liang and Hartman have written comprehensive reviews on the subject.^{4,5}

Certain claims may cause a product to qualify as a drug, even if the product is marketed as if it were a cosmetic. Such claims establish the product as a drug because the *intended* use is to treat or prevent disease or otherwise affect the structure or functions of the human body. Some examples are claims that products will restore hair growth, reduce cellulite, treat varicose veins, or revitalise cells.

Under American law, a product can be considered both a cosmetic and a drug. OTC drugs are often marketed side by side with cosmetics, and some products qualify both as cosmetics and as OTC drugs. This may happen when a product has two intended uses, with ingredients intended to do two different things. For instance, a shampoo is a cosmetic, since its intended use is to cleanse the hair. An antidandruff treatment is a drug, since its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Among other cosmetic/drug combinations are toothpastes

that contain fluoride, deodorants that are also antiperspirants, and moisturisers and makeup marketed with sun-protection claims.

There has been criticism of the rigidity of the statutory definitions and the FDA's approach by both professionals and the cosmetics industry. In 1979, Kanof proposed a redefinition of the word "cosmetics"⁶ She argued that the definitions of "drugs" and "cosmetics" differentiated on the premise of intent to affect the structure and function of the skin, but failed to contemplate two critical facts. First, in the intended use of the products, a drug is directed to pathological activity but a cosmetic is intended to alter a state of physiological activity from less agreeable to more agreeable. In both instances, the structure and/or function are affected (altered). She argues that differentiation between cosmetic and drugs cannot be based on intent to affect structure and/or function, since both cosmetics and drugs do affect the structure and function of the skin. Second, the present definition of cosmetic does not recognise the dynamic nature of the skin and its structural capacity to accommodate both natural and man-made environmental exposures. Support for Kanof's argument can be found on many cosmetic products where there are at least allusions to modifying the physiology of the skin.

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4. REGULATION OF PRODUCT CATEGORIES UNDER THE JOINT REGULATORY SCHEME FOR THERAPEUTIC PRODUCTS

4.1. ANTIPERSPIRANTS

Topical antiperspirants typically contain inorganic salts of aluminium, zinc or zirconium, usually as chlorohydrates that are in some cases complexed with organic moieties. They are sold as roll-ons, lotions, creams, pump sprays and aerosols. Some organic substances such as diphenanil methylsulphate (now discontinued) have also been used in dusting powders for the treatment of frank hyperhidrosis.

Deodorants that are not antiperspirants usually rely on the presence of alcohol with perfumes as masking agents, or an antibacterial agent such as triclosan or zinc phenolsulphonate. Antiperspirant products are deodorants by reducing the extent of sweating with or without the presence of perfumes. Some products containing Al, Zn and Zr salts describe themselves as "Antiperspirant Deodorant" and may do so legitimately because they also contain perfumes to mask body odours and because aluminium has some antibacterial activity.

The market

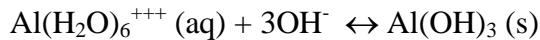
About 100 million units of antiperspirants are sold each year in Australia and about 20 million in New Zealand. The UK market for antiperspirants, deodorants and body sprays is estimated to be £447 million. This represents about 30 per cent of the toiletries sector which makes up almost a third of the entire cosmetics market.

Chemistry

The chemistry of the aluminium-containing antiperspirants is more complicated than it might first appear. At below pH 3, the Al^{+++} ion forms a mononuclear species hydrated by six water molecules attached by oxygen atoms around the Al ion in an octahedral geometry, thus:



Under higher pH conditions, from pH 4-8, the mononuclear species is not formed. Instead, hydroxylation of the inorganic salt occurs and various amorphous polymeric species of aluminium hydroxide species are possible.



These range from small species such as $\text{Al}_2(\text{OH})_2^{++++}$ to much larger species such as $\text{Al}_{13}\text{O}_4(\text{OH})_{24}^{++++++}$. With the onset of sweating, the aluminium salt dissolves into the neck of the sweat duct. The average pH of axillary sweat is about 6, so the aluminium salts form polymeric aluminium hydroxide solids. These form a gel, which blocks the sweat gland duct thus reducing the amount of sweat secreted. The presence of gel plugs has been confirmed by using analytical methods, eg transmission electron microscopy.

In 1950, zirconium (IV) salts were patented in antiperspirants. Zirconium salts have similar chemistry to aluminium salts in that they form gels on hydrolysis. They tend to be slightly more efficient than aluminium salts because of the higher acidity and greater coordinating power of Zr^{++++} -containing complexes. Zirconium salts, however, are too expensive to use as the sole antiperspirant active but incorporation of a small amount of zirconium oxydichlorohydrate ($ZrOCl_2$) or zirconium oxyhydroxychlorohydrate ($ZrO(OH)Cl$) in aluminium chlorohydrate ('ACH') -based antiperspirants improves their efficacy by 30-50 per cent. These zirconium/aluminium chlorohydrate ('ZACH') salts are more acidic than ACH and therefore need to be buffered to reduce skin irritation. This led to the development of zirconium aluminium glycine or 'ZAG' salts; these are 'ZACH' salts complexed with glycine (aminoethanoic acid), which buffers 'ZACH' salts without hindering performance.

A more recent development was the production of inorganic polymers having a higher proportion of smaller polymers, which leads to increased efficacy. A similar process was developed for 'ZAG' salts in the 1980s, which produces 'activated' 'ZAG' salts that are used in non-aerosol products.¹

Unwanted effects

There are few reports posted on MEDLINE of adverse effects associated with these substances, although local irritation is possible. Most brands sold in Australia carry non-mandated statements such as "*Do not apply to broken or irritated skin*", "*CAUTION. KEEP OUT OF REACH OF CHILDREN. Do not apply to broken irritated skin. If an irritation develops discontinue use*", "*CAUTION: Do not apply to irritated or damaged skin. As with all anti-perspirants, discontinue use if rash develops*". Industry has adopted one or more of these statements in line with the FDA's monograph.

There have also been rumours of a link between the use of antiperspirants and breast cancer that have been the subject in the daily press.⁶

In August 2003, the Medicines Evaluation Committee considered a new FDA mandatory warning statement to go on the labels of antiperspirants "Ask a doctor before use if you have kidney disease" (due to the presence of aluminium). The Committee decided that this was not necessary since people with significant renal impairment would be under treatment from a specialist who would advise them of the necessary precautions.

Legislative considerations

Under Australian law, antiperspirants are considered to be therapeutic goods because the definition of therapeutic use under the *Therapeutic Goods Act* 1989 includes: "...influencing, inhibiting or modifying a physiological process in persons ...".

While the reference to "a physiological process" brings antiperspirants within the scope of the Act, they are minimally regulated within its framework by being described as "exempt goods". The word "exempt" means that, unlike most therapeutic goods, antiperspirants are not entered in the ARTG and can be lawfully supplied without being so entered. A further regulation also exempts manufacturers of antiperspirants from the

usual requirement of having to be licensed by the TGA. They are subject to TGA recall procedures and advertising clearances. The only significant requirement is that the name and concentration of the active agent must appear on the label together with the sponsor's name and address.

Returning to the definitions of "therapeutic goods" and "therapeutic use", it is important to consider also the lead-in words in relation to "influencing inhibiting or modifying a physiological process in persons". Omitting those words that are not relevant to antiperspirants,

therapeutic goods means goods that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be influencing, inhibiting or modifying a physiological process in persons.
[Underlining added].

Viewed in this light, it is arguable whether a typical antiperspirant would be "likely to be taken to be influencing...in persons". The definition begs the question – "Likely to be taken by whom?" Is it the manufacturer, the regulator, the seller or the purchaser? It is submitted that it is the ordinary person who wants to buy something to apply to the axillae to minimise body odour and unsightly sweat marks on the clothing. If this is the case, antiperspirants might be considered as outside the statutory definition of therapeutic goods even though the Al, Zn or Zr salts have a physiological action.

The question of the meaning of the word "likely" was considered by the Federal Court of Australia in 1997 on appeal from a decision of the Administrative Appeals Tribunal which had had to consider the interpretation of the word "likely" in relation to a regulation that provided for unacceptable presentation of therapeutic goods.² The Court upheld the Tribunal's finding that "likely" meant "probable", "as seeming as if it would happen" or "a substantial or real and not remote chance". In the context of the *Therapeutic Goods Act 1989*, it did not mean "more likely than not", "a more than 50% chance of a thing happening" or "odds on". The dictionary defines "likely" as "1. such as might well happen, or be or prove true, or turn out to be the thing specified, probable. 2. to be reasonably expected to; promising, apparently suitable for purpose or to do or be... 3. probably".

A case that has some parallels with the action of antiperspirants considered the question of whether tampons were, or were not, therapeutic goods (devices) within the meaning of the Act. In 1992, the Administrative Appeals Tribunal found that because tampons interfered internally with the natural passage of menstrual blood, they fell within the definition of therapeutic goods.³ On this reasoning, because antiperspirants interfere with the natural passage of sweat from the sweat glands, they too should be regarded as therapeutic goods. Unlike tampons, where the risk of toxic shock syndrome was an issue, the risks associated with antiperspirants are minimal.

The statutory definition aside, antiperspirants unquestionably behave in the market place as cosmetics or toiletries. They are stocked with grooming aids and the like; the get up is not remotely like a medicine and there are no references, express or implied, to prophylactic or therapeutic indications on the label or in advertising. Applying the test in *Ribena*, antiperspirants are "...mainly and generally at any rate on the market for, normally healthy persons; sold neither therapeutically nor prophylactically...".

Sweating is an essential and normal body function. Antiperspirants are used for aesthetic reasons and not for the prevention or treatment of any disease or the alleviation of their symptoms.

In Australia, Canada and the USA, antiperspirants are treated as falling within the definition of “therapeutic goods” or “drugs”. In New Zealand and the EU, they are cosmetics. In South Africa, an antiperspirant “modifies a physiological function in that it inhibits the production of perspiration. Its purpose is the prevention of body odour that will occur if perspiration is unchecked. Although it acts by the modification of a physiological function, this modification is minor and is at a superficial level. This product is classified as a cosmetic”.⁴

The kinds of antiperspirants under consideration appear to be a class of goods where common sense should be accorded more weight than a narrow interpretation of paragraph (b) of the statutory definition of “therapeutic use”. It is inevitable that in an area as complex as the regulation of chemicals (in their widest sense), substances or classes of substances will be caught up in a definition when common sense otherwise suggests. Indeed, in 1972 in his oft-quoted lecture, “The Judge as Lawmaker”, Lord Reid said: “we should, I think, have regard to common sense, legal principle and public policy in that order. We are here to serve the public, the common ordinary reasonable man.”⁵

Given the minimal regulation prescribed by the Therapeutic Goods Regulations 1990, it is but a short step to exclude antiperspirants from the operation of the Act and, when the Joint Agency is in operation, to exclude antiperspirants. It is possible that future products might be formulated as antiperspirants that contain ingredients other than those proposed for classification as cosmetics. These should be regulated as Class II medicines under the Joint Agency arrangements.

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.

References

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3. *Johnson and Johnson Australia Pty Ltd v. Minister for Aged, Family and Health Services* No. A91/146 AAT No. 8295

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4.2. ANTIDANDRUFF TREATMENTS

There is no definitive cause of dandruff. There is an increased turnover of epidermal cells and drugs such as selenium sulphide, pyrithione zinc are thought to act by reducing the turnover of them.¹ Various species of fungi are also implicated and pyrithione zinc has antifungal activity. Dandruff, or rather its cause, can be suppressed successfully but it is difficult to eliminate. It is unsightly, causes itchiness and is a nuisance; it may encourage excessive scratching leading to skin infection. Another view is that it is a social, rather than a health problem. More serious cases might better be described as seborrhoeic dermatitis, in which case a product with such a claim would require registration.

Shampoos must contain more than detergents to enable an antidandruff claim to be made. Among the drugs used to treat dandruff are tars, selenium sulphide, salicylic acid, resorcinol, piroctone olamine, cadmium sulphide, sulphur and the azoles. Climbazole, used in concentrations of 0.5 to 1 per cent, is an ingredient of some shampoos on the European market. The most commonly used active agent in “mass market” antidandruff treatments is pyrithione zinc, usually at a concentration of one per cent, although two per cent was formerly used. Shampoos are the most common vehicles and some brands also incorporate a conditioner. Correct application of any of them is required for effective suppression of dandruff.

In Australia, the regulatory controls on products containing pyrithione zinc have been successively relaxed. For many years, they were included in the poisons schedules; those containing > 2% were Schedule 2 poisons and those of ≤ 2% were in Schedule 5. Pyrithione zinc in the concentrations used for the prevention and treatment of dandruff normally fall under Schedule 2 to the Standard for the Uniform Scheduling of Drugs and Poisons but certain preparations are exempted from this classification by the so-called “reverse scheduling” i.e. the substance concerned is not in the Schedule subject to conditions, such as the inclusion of two warning statements on the label. In the case of pyrithione zinc, the Schedule 2 entry reads:

PYRITHIONE ZINC for human therapeutic use, except:

- a) in semi-solid hair preparations; or
- b) in shampoos containing 2 per cent or less of pyrithione zinc when labelled with the statement, “keep out of eyes” or “If in eyes rinse well with water”.

Under the Therapeutic Goods Regulations 1990, they are minimally regulated as “exempt goods” because of their low toxicity.

There is currently a problem of potential inconsistencies in labelling between products that are included in a poisons schedule in one strength (and therefore fully evaluated by the TGA) and exempt (therefore not evaluated by the TGA) in another. This anomaly is currently being discussed with stakeholders. It would be even more confusing for consumers and industry if low strength products were regulated as cosmetics and higher strengths of the same product as medicines.

What are these products on the market? Why do people buy them? Are they a medicine formulated in a cosmetic vehicle or a cosmetic that has an incidental therapeutically

active substance in the formula? Would a person who does not have dandruff buy them to wash his or her hair in preference to formulations that are surfactants or surfactants with conditioners?

Just because a topical product intended to treat or prevent a therapeutic condition is very safe and widely used does not make it a cosmetic. An ointment consisting of a mixture of paraffins is still a therapeutic good if it is intended for adjunctive treatment of psoriasis or atopic eczema and it would be hard to imagine anything blander. A nasal spray that is simply normal saline is classed as a therapeutic good.

And what of the term “mass market”? Does that suggest that because something is popular, it should influence how it is classified? Unscheduled analgesics and antacids are “mass market” but no one would seriously suggest that they should be treated as other than therapeutic goods. This Report is of the view that the description “mass market” is irrelevant to the debate on whether an article is more appropriately regulated as a therapeutic good or a cosmetic.

Unlike antiperspirants, it is difficult to regard shampoos that contain pyrithione zinc 0.5 to 2% as anything other than a therapeutic good. One brand of pyrithione zinc shampoo (Dan Gard) is a Repatriation Pharmaceutical Benefit. It is of course true that these products are perfectly good shampoos but their primary purpose in the market is the prevention and treatment of dandruff, a condition that people would rather not have. It is also true that dandruff is not a serious medical condition. It is not, however, self-limiting and although a shampoo base is used to deliver the pyrithione zinc, the efficacy of this substance is enhanced if the scalp and the hair are clean. Now it could be argued that no harm is done if these products were excised from the *Therapeutic Goods Act* 1989, especially as they are minimally regulated under the Act. What then? Do they default to a cosmetic because “cosmetic product” mentions the cleansing of the hair? The Report considers that it is stretching regulatory interpretation too far to classify antidandruff shampoos as cosmetic products and that the present definitions of “therapeutic goods” and “therapeutic use” are the correct ones to apply to pyrithione zinc and other substances when dispersed in a shampoo vehicle, lotion or hairdressing base for the prevention or treatment of dandruff.

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,

- (c) the product should be exempted from licensing; and
- (d) the premises where the product is manufactured should be exempt from licensing.

References

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4.3. SUNSCREEN-CONTAINING PRODUCTS

Sun protection is to be taken more seriously in Australia than anywhere else in the world because a coastal-dwelling, predominantly European population inhabits a country with ample sunshine and more and better accessible beaches than most. There is also the hole in the ozone layer that reduces protection. That Australia has the highest rate of skin cancer in the world is well known. School children are required to have a bottle of sunscreen and hats as part of their kit; governments have funded the “Slip, Slap, Slop” campaign and children often wear “zoot suits” at the beach to give greater protection against the harmful effects of the sun’s rays.

The ARTG has about 1,200 sunscreen-containing products, nearly all of which are Listed Goods. The market is very competitive. Some products are made by leading international cosmetic houses, some by pharmaceutical manufacturers and others for supermarkets, the latter often being available in one litre containers at low prices. Contract manufacturing is common in the sunscreens industry. There is considerable market segmentation as shown by sunscreens whose use is directed to particular groups such as children and sunscreens that are sponsored by bodies such as sports organisations.

International comparison of sunscreens regulation

Table 1: Summary of international controls on sunscreens.

	Australia	Canada	EU	Japan	NZ	South Africa	USA
Class	Therapeutic	Therapeutic	Cosmetic	Cosmetic	Cosmetic	Cosmetic	Therapeutic
Product approval	Yes	Yes	No	No	No	No	No
Manf'g Licence	Yes	Yes	No	No	No	No	Yes
Evaln of actives	Yes	Yes Monograph	Yes Annex VII	Yes	No	No	Yes Monograph
Evaln of excipients	Yes	No	No	No	No	No	No
Expiry date	Yes	Yes	No	No	No	Only if < 30 months	Only if < 36 months
Test - UVA	Yes	Unresolved	Unresolved	Yes	Yes	Unresolved	Unresolved
Test - UVB	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SPF Range	2-30+	2-30+	2-30+	To 50+	2-30+	2-30 & above	2-30+

In Europe and New Zealand, all sunscreens are treated as cosmetics but the extent of regulation differs markedly. In the EU, as shown by the UK regulations, there is an elaborate regime. For example, although there is no manufacturing licence required, the Regulations require compliance with good manufacturing practices and while the final products are not “approved” by the government before they enter the market, there are nonetheless obligations placed on manufacturers or domestic sponsors of cosmetics. (see UK/EU chapter).

In Canada, sunscreens are drugs.

In the United States, the FDA treats sunscreens, and moisturisers that contain sunscreens, as both drugs and cosmetics.¹ In other words, the laws applying to both classifications must be observed. In 1999, the *Federal Register* stated (at page 27673):

“The agency [FDA] agrees that all sunscreen products (whether drug only or drug-cosmetic) should be held to the standards (e.g., active ingredient(s), testing requirements and labeling). Regardless of what type of product a consumer chooses for sun protection, the essential information relevant to sun protection is the same. Thus, to ensure that consumers are adequately protected from overexposure to the sun, all products intended for use as sunscreens should have similar labeling requirements, irrespective of whether the sunscreen use is considered primary or secondary to the product.”

Australian regulatory regime for products containing a sunscreen

In Australia, sunscreens and products that contain sunscreens are subject to a complicated set of laws and have the distinction of being classified under the *Therapeutic Goods Act 1989* as Registered Goods, Listed Goods, Exempt Goods and Excluded Goods. The following summarises the situation in Australia:

Group 1 – Sunscreens of SPF of at least 4:

1. for the primary purpose of protecting the skin from the sun’s harmful rays; and
2. for which reference to the prevention of skin cancer may be made; and
3. when supplied as Repatriation Pharmaceutical Benefits; or are for the treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the Therapeutic Goods Advertising Code.¹

These are classified as therapeutic goods. They must:

- (i) be manufactured in licensed premises;
- (ii) comply with the Australian and New Zealand standard in respect of: (a) the claimed sun protection factor as having been established by testing according to the method described in Standard AS/NZS 2604:1998, as in force from time to time; and (b) the performance statements and markings on the label as having complied with that Standard;
- (iii) be entered on the Australian Register of Therapeutic Goods as “**Registered Goods**”; and
- (iv) comply with the Labelling Order for therapeutic goods (which includes the quantified disclosure of the sunscreens, batch number and expiry date).

Each product is evaluated for quality, safety and efficacy. There are only seven of these in the Schedule of Pharmaceutical Benefits, divided between three manufacturers.

Group 2 – Sunscreens of SPF of at least 4:

1. for the primary purpose of protecting the skin from the sun’s harmful rays; and
2. for which reference to the prevention of skin cancer may be made.

These are classified as therapeutic goods. They must:

- (i) be manufactured in licensed premises;
- (ii) comply with the Australian and New Zealand standard in respect of: (a) the claimed sun protection factor as having been established by testing according to the method described in Standard AS/NZS 2604:1998, as in force from time to time; and (b) the

¹ Parts 1 and 2 of Appendix 6 refer to the prohibition on representations about neoplastic disease, except prevention of skin cancer.

- performance statements and markings on the label as having complied with that Standard;
- (iii) be entered on the Australian Register of Therapeutic Goods as “**Listed Goods**”; and;
 - (iv) comply with the Labelling Order for therapeutic goods (which includes the quantified disclosure of the sunscreens, batch number and expiry date).

While the final products are not individually evaluated and are self-assessed by the sponsor, the actual sunscreening agent will have been evaluated by the TGA for safety. Most sunscreens on the Australian market are Listed Goods.

Group 3 – Sunscreens of less than SPF 4:

- 1. **that meet the Australia/New Zealand Standard for Sunscreen Products; and**
- 2. **disclose the SPF on the label; and**
- 3. **do not include an ingredient of human origin, or animal origin if the ingredient consists of, or is derived from, prescribed parts of certain animals.**

While being therapeutic goods by definition (and not therefore cosmetics), they are not entered in the Australian Register of Therapeutic Goods and the manufacturer does not have to be licensed. These are known as “**Exempt Goods**”.

They must comply with the Labelling Order.

Group 4 – Preparations containing a sunscreening substance:

- 1. **if the primary purpose of the preparations is *neither* protection of the skin from injury from solar radiation *nor* another therapeutic purpose; and**
- 2. **provided any representations about the goods do *not* include: (a) a statement of a claimed SPF; or (b) a description of a claimed sun protection category; or (c) a reference to another therapeutic use in respect of the goods.**

Products meeting this description are excluded from the operation of the *Therapeutic Goods Act* 1989 and are classified as cosmetics. Manufacturers are not required to be licensed. In other words, a manufacturer may include a sunscreening agent in the formulation but must not refer to (a), (b) or (c). The manufacturer may state on the label that the product contains a sunscreen and is required to state its name among the list of ingredient in accordance with regulations made under the *Trade Practices Act* 1974. Moisturisers with sunscreens are the main example. If any of these conditions are not met, the product attracts the same regulatory controls as a sunscreen as such.

Group 5 – Preparations containing a sunscreening agent that are “defined in the Australia/New Zealand Standard for Sunscreen Products as secondary sunscreen preparations which are:

- (a) **preparations for application to the lips which are tinted and unmedicated;**
or
- (b) **tinted facial make-up (other than moisturisers);**

and which are not for any other therapeutic purpose”.

In this group, the SPF can be quoted but the products are excluded goods and are classified as cosmetics. Note that the exclusion does not extend to moisturisers.

There appears to be reasonable compliance with the statutory requirements, despite their complexity.

Groups 1 and 2 – Primary sunscreens

The Australian regulatory regime for primary sunscreens was described above. Industry organisations in Australia have not advocated a change in the arrangements but some New Zealand industry bodies are of the view that primary sunscreens should be treated as cosmetics, in the manner of New Zealand and the EU. The difference between New Zealand and the EU is that the EU has a detailed Directive that member states have incorporated into domestic legislation. In New Zealand, there are no legislative controls underpinning what happens in practice. Medsafe has indicated that sunscreens may be treated in New Zealand as therapeutic products in future.

Primary sunscreens are serious products for a serious purpose. While this Report maintains that primary sunscreens should be held to a high degree of quality, safety and efficacy within the scope of therapeutic goods, rather than cosmetic laws, there is a case for querying whether the only acceptable performance standard in relation to the sun protection factor is that prescribed in AS/NZS 2604:1998. Slow progress has been made on uniformity since 1984 when discussions on international harmonisation of the methodologies for the measurement of the SPF for sunscreen products began. It is important that this matter progress quickly. The question is: Is the consumer going to be any the worse off if one of these standards, as it relates to the SPF, were an alternative to the others? If the answer were no and there were functional equivalence across the range of SPFs, any one of these should be acceptable. The Report notes that this is the position in South Africa where, as long as the performance standard meets any one of these, the product is deemed to comply. Griffen *et al* and Lowe *et al* observed in 1997 that the FDA and COLIPA guidelines were very similar. Groves compared the [then] Australian and FDA standards and the differences highlighted the similarities.²

At a conference held in Beijing in November 2004, there were encouraging indications that an internationally acceptable standard would be published in the next 12 months. When this is in place, there is every reason that it should be considered for use as an alternative to AS/NZS. In the meantime, in the interests of minimising uncertainty to industry in Australia and New Zealand, sunscreens that are therapeutic products should work to the present standard.

Neither the EU nor the FDA standards have yet mandated performance standards for UVA or for water resistance. These are believed to be in progress.

Some industry organisations pointed out that Australia is “at the extreme end of the regulatory control spectrum”. This Report submits that Australia should not apologise for the stand that it has taken because of the short and long-term health problems arising from the country’s climate, demographics and beach culture outlined at the beginning of this chapter. Accordingly, there should be no change to existing controls on primary sunscreens, with the exception of providing, in the future, for compliance with alternative prescribed standards in determining the sun protection factor and other performance standards when published.

Group 3 – Sunscreens of less than SPF 4

The Australia / New Zealand Standard AS2604 classifies sunscreens with an SPF of less than 4 as “very low protection sunscreens”. They are currently regulated as Exempt Goods in Australia. The efficacy of these products in terms of sun protection is open to question, especially when the in-use SPF is taken into account.² Sun oils are examples of the products that contain low SPFs, usually about 2. It is difficult to accept that, providing there are no therapeutic representations, these products are therapeutic goods even by definition. If this were so, and the goods were declared as Excluded Goods, a manufacturer would be required to state the unquantified composition on the label in the prescribed format for a cosmetic product but could state, truthfully, that the product contains a sun screening agent. In this circumstance, the absence of the SPF or its description on the label would be unhelpful to the consumer who may think that the product offers more protection than it can deliver. Two options can be considered. The first is to leave them as Exempt Goods; the second is to exclude them from Joint Agency legislation provided the SPF is stated on the label (so as to give consumers the necessary information to assist in making a decision to purchase). The difference is that only the name and concentration of the sun screening agent have to be stated on the main label whereas in the latter, full disclosure of content is mandatory and the concentration of the ingredients do not have to be stated.

These products cannot reasonably be regarded as having realistic and meaningful sun screening properties, especially when in use. Accordingly, the Report considers that these products should be regulated as cosmetics.

Group 4 – Moisturisers with sunscreen

An identical formula of a product that is a moisturiser with sun screening agents can be treated as a Listed Good under the *Therapeutic Goods Act 1989* or as an Excluded Good outside the Act. The classification depends on how the sponsor wants to position the product, having regard to labelling and advertising. For the product to be eligible for classification as a cosmetic (or rather, not a therapeutic good) the *primary* purpose must *not* be:

- a) protection of the skin from injury from solar radiation; and
- b) there must *not* be:
 - any reference to the SPF; or
 - a description of the claimed protection category; or
 - reference made to any therapeutic purpose (including skin cancer).

Subject to satisfying all of these conditions, the product is a cosmetic and has to be labelled in accordance with regulations made under the *Trade Practices Act 1974*.

If one or more of these conditions are not met, the product is a Listed Good and is subject to all of the requirements for Group 2 (above). There are a number of products on the Australian market that are described as, and have the appearance of, moisturisers but inclusion of the SPF on the label is sufficient to make them Listed therapeutic goods.

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 that people rely on for prevention of sunburn and skin cancers.

Moisturisers with sunscreens are secondary sunscreen products. A secondary sunscreen product is defined in the AS/NZS 2604:1998 as “a sunscreen product which is represented on the label as protecting the skin from certain harmful effects of the sun’s rays while fulfilling another primary purpose”.

If the product is within the Act, any excipients (inactive ingredients) must have been approved by the TGA. In considering applications for new excipients, the TGA will consider evaluation reports from other regulatory bodies (e.g. NICNAS, CIR). It is important to maintain this level of assessment because in Australia sunscreens are often used over large areas of the body surface for long periods of time. If a product is outside the Act, by being a cosmetic, all ingredients, but not the final product, will have been assessed by NICNAS.

A 1999 study submitted by the CTFAA concerning consumers’ preferences for the relative importance of attributes of moisturisers with sunscreens showed a ranking of:

- | | |
|--------------------|-----|
| 1. Moisturises | 27% |
| 2. Pleasant to use | 25% |
| 3. Gentle to skin | 16% |
| 4. Anti-Ageing | 10% |
| 5. For mature skin | 10% |
| 6. UV Protection | 6% |
| 7. Other | <6% |

The above attributes are not, however, strictly comparable in that some relate to the purpose of the goods while others to their properties.

The submission also said that 75% of consumers believed a moisturiser with SPF could help protect from sun damage, but indicated, “they would use a sunscreen in direct sunlight”. If, however, these products were permitted to quote the SPF and make a feature of it on the label and in advertising, the relatively low percentage quoted above might well increase.

The CTFAA and ACSPA have also examined market data about seasonal buying patterns of moisturisers containing a sunscreen. The data showed:

- sunscreens sell best in summer;
- moisturisers, including those with a sunscreen in them, sell all year round; and.
- moisturisers with a sunscreen in them tend to grow in the market place at the expense of moisturisers without a sunscreen.

Moisturisers with sunscreen are estimated to occupy 10-15% of the moisturiser market in Australia. The CTFAA’s summary of the position in Australia is: “consumers understand that moisturisers with SPF provide a valuable additional benefit to help protect against intermittent sun exposure and damage but know they are not a substitute for a sunscreen”.

The CTFAA and the ACSPA have identified a number of points that assist in differentiating between moisturisers with a sunscreen and primary sunscreens. A modified version appears in the table below:

Attributes	Moisturisers with Sunscreen	Primary Sunscreens
Delineators		
1. Product descriptor	Moisturiser	Sunscreen
2. Claims/Advertising/ Labels	Primary claim is to “moisturise and protect. Makes skin look and feel good”.	Primary claim is to “use when in the sun to protect from sunburn”. References to skin cancer if SPF >30.
3. Instructions for use	Use daily, morning and night, both indoors and outdoors, in all weather conditions. Apply sparingly.	For use when going into the sun. Apply liberally and frequently.
4. Package design	Mainly for indoor use. Packs are a “fashion statement”. Often in opaque glass jars and usually in volumes ≤ 100 mL or g.	For outside use often, but not always, in larger plastic packs.
5. Ingredient disclosure	Quantified actives and unquantified preservatives.	Unquantified disclosure of all ingredients.
6. Water resistance	Not water resistant.	May or may not be water resistant.
Lesser Differences		
7. In-store display	Mainly in department stores, pharmacies and supermarkets.	Also sold at corner stores, beach kiosks.
8. Store placement	Placed with other cosmetics, incl. moisturisers w/o sunscreens.	Separate displays for sunscreens.
9. Advertising	No therapeutic claims.	Designated therapeutic claims.
10. Body area	Mainly for usually exposed parts of body such as face and hands.	All over use.
11. Sensory properties	Vanishing.	Slightly greasy feel. High viscosity.
12. Seasonality	All year round. Used during cold weather when skin is dry.	Generally during hot weather.

Other less significant factors are pricing, cost per mL, brand loyalty, and if there is an exemption from GST.

To regulate for all of these factors is clearly impossible. It is possible to find examples of exceptions to many of the above points. The food/drug distinction cases considered the total picture. In sum, all of them contribute to determine what the goods are even though one or two individual factors may go against a general trend; the product described in a later section as a “moisturising sun lotion” is a case in point.

Industry bodies in both Australia and New Zealand believe that the current self-regulation in New Zealand is adequate, not only for moisturisers with a secondary sunscreen but primary sunscreens as well. The Australian industry, however, accepts that primary sunscreens should, in Australia at least, be subject to the present regulatory regime.

The Cancer Council of Australia is satisfied with the current regulatory arrangements but expressed concern that if moisturisers with secondary sunscreens were treated as cosmetics, there was the possibility of diminution of standards. This would be valid if there were no conditions but the recommendations (below) should assuage this concern.

New Zealand regulatory regime for products containing a sunscreen

In New Zealand, products described as, or containing sunscreens, are regarded as cosmetics. Accordingly, there is no requirement for ministerial consent before the goods are placed on the market nor are there any manufacturing standards imposed by law. Arising from a number of cases of poor performance, some sunscreens were withdrawn voluntarily or reformulated.

At present, Medsafe has left the cosmetics industry to regulate itself. The CTFANZ has written a “manufacturer’s guide to GMP” for manufacturers of sunscreen that is a diluted version of the TGA’s Code of GMP for Sunscreens. Manufacturers have chosen to comply with the AS/NZS. Medsafe considers that compliance with the AS/NZS would be an acceptable and achievable alternative between a code of GMP for sunscreens and the *status quo* of cosmetics.

Medsafe’s preferred position is:

- a) [primary] sunscreens should be therapeutic products rather than cosmetics; and
- b) there should be a minimal approach to assume product quality and safety.

To achieve these objectives, two models have been suggested. These are:

- a) For primary sunscreens, the requirements should consist of:
AS/NZS + permitted sunscreens + GMP + SPF>15 + permitted claims + label compliance;
- b) For moisturisers that contain a sunscreen, the requirements consist of:
AS/NZS + permitted sunscreens + SPF ≤15 + very limited claims.

Sunscreens, provided permitted actives are used, are safe. The issue of efficacy is all important because product failure can lead to serious burning and/or, in the longer term, skin damage, including skin cancers. Efficacy should therefore form part of any objectives in the regulation of sunscreens, both primary and secondary. This Report does not share the view that moisturisers should be limited to a SPF of ≤15 for the reasons given below but otherwise supports the general thrust of the proposal.

“Purpose of the goods in the market” test

Using the food/drug interface as a model, the courts in Australia and England have formulated the test of “what is the purpose of the goods in the market at a particular point in time?” A similar test might be applied to goods that share the features of therapeutic goods and cosmetics.

If a product for application to the skin has the purpose of being a moisturiser and only a moisturiser, and the get up of the product looks like, and is advertised as a cosmetic, it will be so regarded. There should not be any dispute about this proposition.

Suppose, however, that the circumstances above are the same except that the formulation contains sunscreens. How would the ordinary consumer regard the product? It is suggested that the ordinary consumer would regard it as a cosmetic because that is the way it looks and because the statements on the labels and in

advertising are consistent with the ordinary person's understanding of what a cosmetic is. The customer is likely to prefer the sunscreen-containing product only if she wants the added benefits that the presence of sunscreening agents may confer, even though her main reason for buying it is for its moisturising properties. Otherwise, she would buy a product that is for moisturising purposes only. If she buys the combination product, she is reasonably entitled to expect that as well as any moisturising benefit, she should also be confident that her skin will receive more protection from the sun's harmful rays than if she used an ordinary moisturiser.

An examination of several products at a suburban supermarket in Wellington, New Zealand highlighted the problem facing regulators in those countries where moisturisers with sunscreens are treated as therapeutic goods.

Product No. 1 This was titled "Moisturising Sun Lotion" and was available with SPFs of 16 and 20, packed in plastic bottles of 200 mL. They contained vitamin E and UVA and UVB filters. The lotion was also described as being water resistant. On the back of the label was the following table, with one cell shaded:

Basic protection SPF 2-5	Medium protection SPF 6-10	High protection SPF 11-15	Intensive protection SPF 16-20	Sunblock SPF 21-30+
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There were several statements about how to use the product, including the advisory sentence: "To extend protection time, use a higher SPF". The claims centred on prevention of photo-ageing and "active cell protection". There were no references to skin cancer. The manufacturer's website says that the product "is water resistant, offers a UVA and UVB filter system with 90% UVA-filtration in accordance with the Australian Standard and Vitamin E protecting against free radicals and premature skin ageing, and minimising the risk of UVA-caused sun allergies". The manufacturer was a large multinational European company.

Product No. 2 Labelled as a moisturising cream with SPF 20 in jars of 100 mL. The claim was "Protection against premature ageing effect".

Product No. 3 As for Product No. 2 but presented as a moisturising lotion in bottles of 150 mL.

The company's website has a Q and A page where a question is asked about the suitability of these products as sunscreens. The company says that these are not intended as sunscreens and are unsuitable for use at the beach because they are not water-resistant.

Product No. 4 A tinted moisturiser in containers of 150 mL with SPF 20.

Product No. 5 A "skin naturals stop". "Anti-ageing multiaction moisturiser SPF 15. Protects against UV rays".

Product No. 6 (seen in an Australian supermarket). The front of the main label bore the words "[Brand name] complete UV Defence moisture lotion. SPF15. UVA + UVB protection with Vitamin E". This product had its AUST L number on the package. Pack size 150 mL.

Products 2, 3, 4, 5 and 6 "looked" cosmetic despite their high SPFs but No. 1 "looked" more like a sunscreen because of the volume, the price (\$NZ14.71), the SPF table, and

the water resistance property. In other words, the get up suggested a sunscreen but the title on the front of the main label called the product a moisturising sun lotion, not a sunscreen, and there was no mention of skin cancer. However, the word “moisturising” qualifies the description “sun lotion”, so supporting the notion that this product is mainly sold as a primary sunscreen. Under current New Zealand law, this does not matter because all sunscreens, whether marketed as such or in the ways shown above, are cosmetics. In Australia, all would be therapeutic goods. Under a revised Joint Agency scheme, this product might create some difficulty in determining whether it is predominantly a sunscreen or predominantly a moisturiser. The information on the company’s website, when considered in conjunction with the product itself, reinforces the view that it is primarily a sunscreen and should be so regulated.

In an effort to resolve the matter, and with an eye to the future, several regulators in New Zealand favoured a limit of SPF15 for cosmetic products; anything above this would be a therapeutic product; anything less, a cosmetic. The argument is that if a product contains a $\text{SPF} > 15$, then its primary role is as a sunscreen rather than as a moisturiser, no matter what its title. While this proposal has the merit of clearly quantifying a cut-off point, it does not take into account the presentation, the present market offerings and differences in peoples’ skins. Further, the tested and stated SPF relate to standardised laboratory conditions but in reality, the thickness of the sunscreen as applied to the body is markedly less; so much so that the functional SPF under in-use conditions is one-quarter to one-half that on the label.²⁴ Even though the SPF is relatively high in the New Zealand examples, and the presence of a sunscreen is secondary to the product’s primary role as a moisturiser, the consumer is entitled to have a product that meets all the attributes the manufacturer says it has.

In considering the classification, the total picture should be considered as the food/drug cases earlier described have shown. In *Ribena*, importance was attached to how the manufacturer himself described the product. A moisturiser with a secondary sunscreen should be just that, no more and no less. The directions for use, the get up, perhaps the price, the purposes for its use, what the website and other advertising says, the absence of representations about any disease, the relatively small pack size, its limited application to the body, its lack of water-resistance and how it is displayed in shops are all factors to be taken into account, even if it is impossible to assign a weighting to the importance of each. It has to be admitted that there is some subjectivity in deciding which way a product of this nature should be classified as the Canadian Guidelines acknowledge. After examining many such products, the Report concludes that moisturisers with sunscreens look like, and are cosmetics and behave so in the market place.

Concern about a regulatory vacuum

Concern has been expressed that, in the absence of a manufacturing licensing system for cosmetics, anyone can set up a factory and produce a moisturiser with a sunscreen in a manner that does not comply with acceptable manufacturing practices and/or performance standards. It is possible that a person could manufacture a product that purports to be a moisturiser with a secondary sunscreen but is in reality a primary sunscreen. There would be nothing to prevent the label showing pictures of beach umbrellas, lifesaver flags, the surf and so on. In fact, there is nothing to prevent this at present if the manufacturer complies with the current rules about not disclosing the SPF

on the label. While the major cosmetic houses would be expected to manufacture to an appropriate standard, doubt remains about the possibility of unscrupulous, ignorant or incompetent persons putting these products on the market as *de facto* primary sunscreens but evading the usual statutory obligations attached to Listing a product on the ARTG.

If moisturisers with a secondary sunscreen were unconditionally excluded from the operation of the *Therapeutic Goods Act 1989*, there would be something of a regulatory vacuum except for the labelling. Unlike the EU, where there is a comprehensive regulatory regime for cosmetics, the same does not apply in New Zealand or Australia. In Australia, if the products are not regulated as therapeutic goods, there is no specific regime to ensure quality and efficacy; the safety of the ingredients, however, will have been assessed and cleared by NICNAS. It is true that moisturisers with sunscreens are often sold in small packs but there is no restriction on pack size written in the law. There would be no obligation to conduct the appropriate SPF testing and, because the goods are no longer therapeutic goods, the Secretary would not have the power to demand information from the manufacturer.

Another concern is that finished goods of questionable quality might be imported into Australia from countries whose standards are markedly less than those expected. Industry states that most cosmetic companies operate to ISO 9001 and there is a voluntary code of GMP produced by the CTFA with which members are expected to comply but there remains the question of “backyard” manufacturers, both local and overseas.

In a market such as this one, the Report considers that any moisturisers with sunscreen that were made under questionable conditions or whose labelling was deficient or whose claims were beyond those permitted, would be quickly examined and tested by competitors and complaints made to the authorities. If the product was found wanting, remedies exist under the *Trade Practices Act 1974* or Fair Trading Acts and also under the *Therapeutic Goods Act 1989* because the exclusion of this class of goods from the latter Act is subject to conditions. Thus, if a sponsor or manufacturer placed on the market a product that purported to be a moisturiser with sunscreen but the get up of the product would lead a reasonable consumer to think that it was primarily a sunscreen, the goods would be “misbranded”. There would be offences under the *Therapeutic Goods Act 1989* for placing therapeutic goods on the market that were not entered in the ARTG and for carrying out a step in the manufacture of therapeutic goods in premises that were not licensed for the purpose.

A recent Australian incident involving the contents of children’s cosmetics was effectively resolved by use of the *Trade Practices Act 1974*, indicating that this remedy together with assessment of ingredients by NICNAS provides the public with assurances even if they are *ex post*. A further safeguard is that all companies dealing in chemicals, including cosmetics will be identified as part of the LRCC project.

One industry organisation 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. If, however, the statement is false or misleading, there are legislative remedies available in both Australia and New Zealand.

If moisturisers with a secondary sunscreen were treated as Excluded Goods without any conditions and were then subject to the cosmetic labelling regulations, there would be no requirement for compliance with manufacturing standards or any need for the goods to conform to the Australia New Zealand Standard (or corresponding standard), including the necessary tests to validate the SPF. Industry has pointed out that moisturisers with sunscreens are not water resistant as many primary sunscreens are, and that a sunscreen-containing product that was water resistant would not be a *bona fide* moisturiser, no matter what it was called. But a primary sunscreen may or may not be water resistant.

Whether this kind of formulation is treated as a cosmetic or a therapeutic good may not be all that important. Arguments about the “the grey areas” or “borderline products” can be endless and unproductive. What is important for health and consumer protection is that a moisturiser that includes a sunscreen for a secondary purpose and no more, looks and plays the part, is properly described and performs as stated.

In order to reinforce to the consumer that the product is primarily a moisturiser, the addition of a disclaimer or an advisory statement has been suggested. Wording such as “Use a primary sunscreen for prolonged exposure to sunlight” or “Use a primary sunscreen when in direct sunlight”. The addition of a statement of this kind would require manufacturers or their local agents to overstick the goods as supplied in their final unopened pack by the manufacturer. Whether this is over-cautious or treats the Australian consumer as being in need of extra advice that is not required in Europe is questionable. A manufacturer could make a statement of this kind voluntarily. If a disclaimer or extra advisory statement were mandated in Australia, industry would be in a similar position that it now finds itself by having to add an ARTG number.

From a regulatory point of view and to reduce uncertainty for the consumer and manufacturers, it is important to ensure, as far as possible, that primary sunscreens and moisturisers with a secondary sunscreen are differentiated. The same can be said about medicines and cosmetic products generally. Using one attribute such as the SPF by itself is not enough. A range of linked characteristics can be identified to minimise doubt. A similar situation obtains with many entries in the SUSDP where a combination of limits on strengths and quantities and the use of certain label statements enables many products to be subject to less restriction than they otherwise would.

Guidance is obtained by looking at products in the less regulated New Zealand regime as previously described.

A reasonable cut-off volume or weight is of necessity arbitrary but an amount of 300 mL or g should reasonably accommodate *bona fide* moisturisers with secondary sunscreen. The pharmaceutical convention of “solids by weight, liquids by volume” should be applied where the density of the product is greater than one. At the same time, it would prevent manufacturers who sought to evade the law from putting up large packs of products that were essentially primary sunscreens but were masquerading as moisturisers with a secondary sunscreen.

In the case of the SPF, cosmetic products seen in New Zealand had SPFs up to 20. This seems a reasonable cut-off and recognises market realities. Above this value, there may be formulation complications that detract from the cosmetic nature of the product.

If the product claimed to be, or was, water resistant, it must be disqualified as a moisturiser.

Recommendation

4. Sunscreens

A. Primary sunscreens where $SPF \geq 4$ 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.

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

C. Moisturisers that contain a sunscreen as and for a secondary purpose where the $SPF \geq 4$ 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.

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4.4 ANTIBACTERIAL HAND WASHES

Bar soaps, and liquid soaps and detergents containing various antiseptics have been on the market for many years. Some have been promoted on account of their ability to kill bacteria that act on sweat to give it an offensive smell. There are many other products intended for use in hospitals, both in general wards or as pre-operative scrubs, and in health practitioners' consulting rooms. Others have been marketed for routine use as a substitute for unmedicated products. An American report indicates that antibacterial soaps are used in households across the country where they amount to a \$US16 billion-a-year industry. One survey of 23 chain, regional and Internet stores in 10 American states found that antibacterial agents were present in 76 per cent of liquid soaps and 29 per cent of bar soaps available nationally. These authors questioned why there was such a need for consumer use of these products on such a scale.¹ Comparable Australian data are not available but a casual examination of the shelves of Australian supermarkets suggests that fewer such products are sold.

In the home, traditional non-medicated bar soaps now share the market with liquid soaps and detergents in pump packs that are presented with different fragrances. The range will often include a variant that contains an antibacterial agent such as triclosan. Gels containing alcohol as the active ingredient are also available; these do not require the use of water.

How antibacterial hand washes are regulated in Australia and elsewhere

In Australia, hand washes that are described as "antibacterial" are therapeutic goods, irrespective of the purposes for which they are intended. Most must be included in that part of the ARTG for Registered Goods which means that each will have undergone a thorough evaluation for quality, safety and efficacy. Those based on melaleuca (tea tree) oil are Listed Goods. Medicated bar *soaps*, but not liquid medicated *soaps*, are not required to be manufactured in licensed premises. Thus, both liquid medicated soaps (specifically) and liquid medicated detergents (by default) for use on the body must be manufactured in licensed premises.

The regulation of these products in selected countries is shown in Table 2. In Canada and the United States, the presence of an antibacterial agent and mention of the word "antibacterial" (and no more) of themselves, classify the goods as coming within the classification of a cosmetic but if there are antibacterial claims or statements about killing germs, then the product is treated as a drug. If the article is a cosmetic, the purpose of the antibacterial agent raises the question of its real purpose in the formulation.

Antibacterial hand washes are regulated as medicines in Australia. They act to prevent the transmission of disease by killing micro-organisms present on the hands. They are used by healthcare workers, in food handling, and in the community.

Antibacterial hand washes, so described on the label, are fully evaluated by the TGA. They must be:

- tested for antibacterial efficacy when used according to the directions on the product label;

- made by a licensed manufacturer;
- labelled in accordance with the Labelling Order; and
- entered in the ARTG.

They are subject to TGA recall procedures and advertisements must be cleared.

The NICNAS is currently undertaking a ‘Priority Existing Chemical’ review of triclosan – one of the most commonly used antibacterial agents in these products.

Products that contain an antibacterial agent whose labels do not use the words “antibacterial” or “kills germs” or similar related therapeutic claims, are regulated as cosmetic products.

The controversy

The use of, and the need for, antibacterial agents in various household products is controversial. Surface antimicrobial agents are beyond the scope of this Report. So too are any detailed public health considerations over the efficacy and safety of those applied to the body or parts of it. The connection between the development of resistant strains of micro-organisms and the use of biocides, especially triclosan, is the subject of debate.⁸⁻¹³

The Medicines Evaluation Committee has expressed concern over a number of years about the indiscriminate use of topical antibacterial products for household use because of the potential to produce microbial resistance. This is of particular concern in products that contain less than the optimal amount of antibacterial ingredient or are otherwise ineffective. The Australian Society for Microbiology (ASM) has stated that data on whether antiseptics such as triclosan contribute to the development of resistant strains are not yet available but it seems likely that they may do so because the genes regulating both antibiotic resistance and triclosan resistance appear to be closely linked in some pathogenic bacteria. The ASM also advises that there is no good evidence that antiseptic agents kill micro-organisms beneficial to humans, but one must assume that they can. The question has become of such public interest that there are many Internet postings about it; some researchers argue strongly against their routine domestic use; the industry that manufactures them, not surprisingly, takes the opposite point of view.

Subject to their correct application, products of this kind have a legitimate place in child day care centres, nursing homes and in some other specific areas. In Australia, because the products have been evaluated, the user of them in these circumstances can rely on their efficacy if used in accordance with the directions. Usage in these settings is somewhere between their role in hospitals (especially in surgery) and their non-essential place in the home.

The routine domestic use of antibacterial hand washes has raised questions of:

- a) whether they are necessary (or in other words, should they be used as substitutes for soap and water);
- b) does their use promote bacterial resistance to antiseptics and antibiotics; and
- c) whether their use has a deleterious effect on micro-organisms that are harmless or whose presence has, in some way, a beneficial effect in humans?

One view is that:

- a) unmedicated soap/detergent and water is just as effective as formulations containing an antibacterial agent; and
- b) the presence of the antibacterial is not only pointless but has potentially harmful effects.

In 1998, McMurry *et al* asserted that “simple soap and water is the most effective defence against viral and bacterial contamination and infection in the home. These new products underscore the importance of cautious use of both antibiotics and antibacterial products since they are made up of potent chemicals with strong and sometimes dangerous side effects. One of the most insidious results is the additional selective pressure they create which fosters emergence of antibiotic resistance, leading to decreased effectiveness of antibiotic therapy”.² In a somewhat broader appreciation of the issue, Levy states: “We exist in the bacterial world, not bacteria in ours.

Unfortunately, we believe that we can rid ourselves of bacteria when, in fact, we cannot. Instead, we should ‘make peace’ with them. Although we need to control pathogens when they cause disease, we do not have to engage in a full-fledged ‘war’ against the microbial world. Improved antibiotic usage will encourage the return of antibiotic-susceptible, commensal flora and return the environment to what it was before the antibiotic/antibacterial onslaught”.³ An Australian expert has been quoted as saying: “The sale of these antibacterial soaps and detergents preys on people’s fears of bacteria. They’re really not necessary since soaps and detergents help reduce the risk from bacteria anyway. It’s really a mild kind of fraud. There’s no proven benefits (*sic*), and all the available evidence suggests it could be detrimental”.⁴ A similar view has been expressed by the ASM which says: “In most cases soap and water are quite adequate for domestic use and use of antiseptics is overkill. It’s a form of commercial pandering to ‘germ-phobic’ consumers”.

Another view is that:

- a) unmedicated soap/detergent and water is just as effective as formulations containing an antibacterial agent; and
- b) the presence of an antibacterial is pointless but may do no harm, especially in relation to the development of resistant strains of micro-organisms.

A study by Larson *et al* studied 224 households in New York City containing 1,178 people, each household having at least one pre-school age child. Cleaning, laundry and hand washing products were distributed to each; half contained an antibacterial and the other half received an identical looking product without an antibacterial. At the end of 48 weeks, there was essentially no difference between the two groups in the seven infectious disease symptoms surveyed, including runny nose, cough, sore throat, vomiting and diarrhoea. As most of the infections are viral, the results are not surprising but one of the authors said that there may be a popular conception that these products will combat *any* infection.⁵ The American Medical Association’s Council on Scientific Affairs has also questioned their efficacy and relevance but stopped short of discouraging their use. One commentator tartly claimed that this was merely a device used by the AMA to draw fire away from unnecessary prescribing of antibiotics by doctors.⁶

A third view is that:

- a) the connection between the domestic use of these products and the development of resistant strains of bacteria is based on the isolation of resistant mutants in *in vitro* monoculture experiments and is not reflected in *in vivo* studies;
- b) the incorporation of antibacterial agents in hand washes has little or no impact on the patterns of microbial susceptibility observed in the environment; and
- c) their use should be associated with a clear demonstration of added value either to consumer health or to the product. Hygienic products should be targeted to applications for which the risks have been established.⁷

Industry has raised the possibility of legislative recognition of stratifying the extent of controls on antibacterial hand washes on the basis of the purpose for which they intended to be used. Thus, those intended to be used as pre-operative or pre-procedural scrubs should be held to the highest levels of quality, safety and efficacy i.e. treated as they are now as Registered Goods. Those intended for use in the food industry, child care centres and nursing homes would be Listed Goods and those that are sold for domestic use, that is to say, as soap substitutes, should be considered Exempt Goods or Excluded Goods. While there is some logic to this proposal on the basis of a descending order of criticality, it does not dispose of the central issues adverted to earlier. If the second recommendation in this chapter (below) is acted upon and it is found that there are no present or likely future adverse effects on personal or public health, such a reclassification might be considered.

A fourth view is advanced by industry which claims that:

- a) the reduction of the normal flora, both transient and resident, is sufficiently supported to be considered a benefit;
- b) personal cleaning and household cleaning products that contain an antibacterial or antimicrobial ingredient provide extra protection against germs, including those that may cause disease; and
- c) the products do what they are claimed to do – kill bacteria.

What the experts agree on is that emphasis should be placed on hand-washing, hygienic food preparation practices and keeping one's distance from flu-sufferers, to help avoid the more common infections.

Some Australian examples

Claims made on the labels of some antiseptic-containing hand washes for general retail sale show statements, in addition to the toiletry-type attributes, such as:

Product No. 1. Front panel of label: "Kills germs and moisturises" The word "antibacterial" is in a frame. The name and concentration of the antibacterial agent and the AUST R number are shown.

Back panel of label: "...is specifically formulated to kill germs on hands"

Product No. 2. Front panel of label: "Hygienic liquid wash". The title includes the brand name of arguably the best known household antiseptic product.

Back panel of label: "Helps to remove germs leaving skin hygienically clean and fresh". There is an unquantified list of the ingredients, one of which is chloroxylenol. Television advertising of Product No. 2 clearly alludes to protective properties.

Product No. 3. This is a herbal skin wash that contains an unspecified concentration of tea-tree oil. There is no ARTG number on the label. The label states: "To help reduce bacteria that may aggravate skin conditions. Tea-tree oil is an effective natural germicide enhancing skin hygiene".

What is the difference? In Product No. 1, there is a clear antibacterial claim but in Product No. 2, the product makes no reference to antibacterial properties other than to say that it "helps to remove germs". If Product No. 2 is simply a hygienic hand wash, why is it necessary to include chloroxylenol? "Hygiene" means "principles of maintaining health; practice of these, eg. by cleanliness" (Concise Oxford Dictionary). Expressions such as "hygienically clean" are tautologous. Product No. 3 may use tea-tree oil merely as a fragrance but the other words make more than an implied therapeutic claim. Further, it is true that tea-tree oil is a "natural germicide" but the product itself is not tea-tree oil; it is a solution that contains an unspecified concentration of it. It may or may not be germicidal.

Using the NCCTG principles on classification, the composition of Product No. 2, because it contains chloroxylenol (of unstated concentration), would suggest that it is a therapeutic good but the proposed use suggests a cosmetic product. Reference to the Table in the NCCTG Guidelines under cleansers indicates that Product No. 1 is clearly a therapeutic good but Product No. 2 is a toiletry or cosmetic product. One kills germs, the other is said to merely help to remove them, as can a surfactant and water. Product No. 3's classification is ambiguous. Like Product No. 2, it reduces bacteria but like Product No. 1, the statement about tea-tree oil being an effective natural germicide invites a person to think of it in that light. If the second alternative prevails, Product No. 3 should be Listed on the ARTG.

How can any reasonable member of the public be expected to draw any distinction between the purposes for which these three products are on the market? And if the purpose on the market of Product No. 2 is mainly and generally for uncomplicated hand washing in the usual domestic circumstances, the relevance and purpose of the presence of an antibacterial agent must be questioned. The presence of antibacterial agents in hand washes for routine domestic use is simply a marketing tool to extend the range in the manner of a new fragrance. And if it does not add a real, and not simply a superficial marketing benefit, does it do any harm?

The concern that has been expressed about the unnecessary and widespread use of antibacterial hand washes needs to be intensively studied from the point of view of public health. The issues are two-fold. First, although antibacterial hand washes for domestic use are held to a high level of evaluation for safety, quality and efficacy, should not their use be targeted in some way to those circumstances where they are really needed? In short, these are serious products intended for a non-serious purpose with potential health implications. That they are individually evaluated in Australia (with the attendant costs) may have acted as a deterrent to their wider use by the general public. Second, those products that are sold as toiletries but contain an antimicrobial agent are in a sense, more insidious and their existence in the market should be questioned.

A regulatory agency might not see that it has a role in making judgments on whether there is a justifiable place in the market for products that are outside the legislation that it administers. The matter may be beyond the Terms of Reference and accordingly, the Report is unable to make a recommendation on it but nonetheless, believes that it needs to be addressed in another forum.

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):

- (c) gives rise to the development of resistant strains of bacteria;
- (d) 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.

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4.5 ACNE WASHES

Under the *Therapeutic Goods Act* 1989, unmedicated soaps and detergents are excluded from the Act and are considered as cosmetic products but if the label claims that the product will prevent, stop or heal acne, irrespective of the product's composition, the product falls within the definition of "therapeutic use". The NCCTG Guidelines, however, regard a statement about "acne-prone" skin as being sufficiently distant from a therapeutic claim under paragraph (a) of the definition of "therapeutic use" (see Appendix) to enable them to be outside the Act. Statements such as the removal of oil from the skin and the covering of comedones or blemishes are also considered as cosmetic.

Unmedicated anti-acne cleansers are already regulated at a very low level by the TGA if, and only if, they have "only a cleansing action or purpose". They have to comply with medicines labelling requirements but they do not need to be entered on the Australian Register of Therapeutic Goods (ARTG) and the manufacturer does not need to be licensed provided the goods are not scheduled in the SUSDP. They are subject to TGA recall procedures. Even though many of these products are mainly detergents, they are therapeutic goods because of a representation about acne (other than acne-prone skin). In other words, they are Exempt Goods.

In New Zealand, anti-acne face washes are generally regarded as cosmetic products, including those where there is a reference to spots and pimples. If the formulation contains additional substances that have a physiological action, such as 2% salicylic acid, the product would be considered a medicine.

Composition of acne washes.

Formulations usually contain surfactants, fragrances, colourings and a preservative dispersed in a vehicle. Some contain an antibacterial agent; others may contain an organic acid such as salicylic acid. As well as any references, however worded, to acne, there are typical cosmetic-like statements such as "deep cleansing" and "cleaning pores". The decision on how the product should be positioned is left to the manufacturer. It depends on the wording and also the composition. By mentioning "acne-prone skin", the manufacturer is segmenting his market to persons who happen to have acne but there is nothing to state that the same product offers a treatment even if the cleansing action of the detergents assists in reducing the likelihood of pimples developing.

How subtle changes in wording can alter the regulation of antibacterial face washes is afforded by these examples:

Product No. 1 is described as a daily face wash. It contains phenoxyisopropanol 2% and the label states: "may help prevent pimples" and that it has antibacterial properties. It is a Registered Good.

Product No. 2 is described as a "sensitive daily face wash" and is made by the same company. Like Product No. 1, it contains phenoxyisopropanol but in an unstated concentration. There are no antibacterial claims but the wash "helps prevent pimples without over drying" and "helps remove oil and pimple-causing bacteria". This is

presumably a cosmetic product rather than an Exempt Good because the contents are fully disclosed in the manner prescribed for cosmetic products.

Product No. 3 is an antibacterial face wash containing triclosan 1%. It is said to aid in the treatment of acne and pimples and assists in the removal of bacteria which can cause these skin problems. This is a Registered Good.

The Canadian *Guidelines for Cosmetic Advertising and Labelling Claims* advise as follows for acne-prone skin products thus:

Acceptable Claims for a Cosmetic	Unacceptable Claims for a Cosmetic
Cleaner for acne-prone skin	Prevents acne
Hides acne	Heals acne
Covers blemishes	Treats acne
Removes oil	Stops acne
	Germ killing action
	Antibacterial action

It would be hard to accept that a consumer (usually a teenager), no matter how discerning or perceptive, would know or care about such differences. The key words are surely “acne” or “pimples”. There is a case for treating products such as Product No. 2 as a therapeutic good. There is no antibacterial claim and no direct claims for acne as such. The formulation begs the question about the purpose of phenoxyisopropanol in it. There is also a question of fairness in the market place. Note the similarity between this state of affairs and handwashes that contain an antibacterial but make no direct claims.

The Report’s Terms of Reference refer to *antibacterial washes* for acne rather than to other anti-acne products. Some comments about cosmetic products that contain active ingredients are in the appendix to this chapter.

The question is: Should antibacterial acne washes continue to be Registered (Class II) Goods?

The options are to treat them as Excluded Goods, Exempt Goods, Listed Goods or leave them as they are. Given that representations are made for a therapeutic purpose i.e. acne, the goods concerned remain “therapeutic goods” and should not be Excluded from regulation by the Joint Agency.

In some respects, their low risk nature might see them as candidates for reclassification; after all, some acne products that happen to contain an antibacterial are positioned as cosmetics already, as in Product No. 2 (above). *Unmedicated* acne washes are Exempt Goods solely because of their representations about acne. To regulate medicated products similarly would remove any regulatory distinction between them.

If a manufacturer wishes to promote his product by way of showing that the antibacterial activity of the product is responsible for the treatment or prevention of acne, the product must be Registered. In the absence of Registration, one can forecast spurious claims being made for products that contain an antibacterial agent as being proven useful for acne. At present, sponsors have to show a causal relationship between the intervention and any improvements in the condition. If a connection is not demonstrated for the particular formulation and not just the substance, the goods will not be Registered. Such a connection does not have to be provided for Listed Goods and

Exempt Goods. Further, in such a sensitive market, the user is entitled to expect that the claims made for the goods are genuine. While Listed Goods have the advantage of ensuring that the manufacturer complies with the Code of GMP, there is little real control exerted on the claims and there is no evaluation in an area that lends itself to exaggerated claims and promises.

This Report concludes that the present regulatory regime in Australia is appropriate and reasonable for antibacterial acne washes. To liberalise it would enable manufacturers of acne washes to make claims that are for frank therapeutic use without any real evidence that the product, and specifically the antibacterial agent in it, does any good. Elsewhere, the Report has expressed concern about the inappropriate use of antibacterial agents.

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.

Appendix – Active ingredients in skin washes

Most cosmetics, such as lipsticks, blushes, eyeliners and moisturisers rely on the formulation in its entirety to bring about the desired effect. Unlike most medicines, there are not usually one or more specific active ingredients in a cosmetic, except in the case of cleansers that rely on the presence of surfactants. Some cosmetic products do have identifiable active ingredients, some of which are also used in preparations that are unquestionably medicines. Salicylic acid is an example. One product that was examined was described on the main label as an “oil-free acne wash” and was a “gentle yet effective cleanser for acne-prone skin”. On the basis of these statements, it is a cosmetic but on the information panel, the wording goes further than that on the main label because it says the product “helps to prevent blemishes by removing excess oil and surface buildup”. The wording goes on to say, “For uncomplicated acne involving only the face”. The product contains salicylic acid 2% and is cited as the “active ingredient”. Salicylic acid in concentrations of this order is used in clinical dermatology; examples are Salicylic Acid and Sulphur Cream APF (1%), Salicylic Acid Lotion, Compound APF (2.5%), Benzoic Acid Ointment, Compound APF (3%) and others; dermatologists prescribe salicylic acid in alcohol as a “peeling lotion”.

There is, however, no reason why a cosmetic product should not include one or more identifiable active agents that in another presentation would be seen as a medicinal preparation; for example, witch hazel (*Hamamelis* Water BPC) has long been used as an astringent in toilet preparation but was formerly used as a cooling application to sprains and bruises and also as a haemostatic.

This kind of formulation further highlights the difficulty in defining a precise interface between cosmetics and medicines, especially when a physiological change takes place.

4.6 TOOTHPASTES AND MOUTHWASHES

Toothpastes and tooth powders

Pastes and powders for use on the teeth (excluding false teeth) can be divided into those containing:

1. abrasives, surfactants and flavours;
2. as in 1 with a fluoride salt;
3. as in 1 or 2 with a desensitising agent;
4. as in 1 or 2 with sodium bicarbonate and peroxide;
5. as in 1 or 2 with an antibacterial e.g. triclosan.

Gels are also on the market.

Of these four categories, only the third is regulated in Australia as a therapeutic good; the others are excluded from the operation of the *Therapeutic Goods Act 1989* by Order and they are no longer therapeutic goods by definition. They meet the definition of “cosmetic product” and are regulated accordingly in terms of the label content.

With regard to desensitising toothpastes, these are purchased when there is a specific need; namely, the unpleasant reaction the consumer experiences when eating foods or drinking beverages that are very hot or cold. Potassium nitrate and strontium salts are most commonly used. There is some controversy about whether they provide an advantage when compared with an ordinary fluoride toothpaste.¹⁻²

Industry has argued that because the fluoride in most toothpastes fulfils a more important therapeutic role than those that include desensitising agents, the latter should also be treated as Excluded Goods. In Australia it is certainly true that the representations for fluoride toothpastes are captured by paragraph (a) of the definition of “therapeutic use”, and under the former Victorian registration scheme for proprietary medicines, (*Health Act 1958*) fluoride toothpastes were subject to registration. An early policy decision was taken to treat them as Excluded Goods under the *Therapeutic Goods Act 1989* perhaps because of a public health need on a continuous basis with minimal regulatory intervention such that non-fluoridated toothpastes are now the exception. It is also true that desensitising toothpastes pose little risk but they are nonetheless therapeutic goods that are used generally episodically, rather than continuously. The public does not need to be exposed to potassium nitrate and strontium salts unless there is a dental indication. Absence of risk or at any rate, low risk, does not transform a medicine into a cosmetic product. Should desensitising toothpastes then be treated as “Exempt”? A licence to carry out a step in the manufacture of the goods would no longer be required and the goods would no longer be entered on the ARTG. Such a reclassification would mean that manufacturers would no longer have to prove efficacy and could incorporate untested chemicals into the formulation.

Dentists often recommend the use of desensitising toothpastes. Both the public and the profession should be entitled to expect that sponsors of desensitising toothpastes have adequate data to satisfy the criteria of safety and efficacy.

Mouthwashes

There are several kinds of mouthwashes:

1. flavoured solutions, including drops that may or may not contain fluoride, for freshening the breath;
2. as in 1 and containing an antiseptic with claims limited to freshening the breath and combating plaque;
3. antiseptic solutions that have been proven to reduce the development of plaque formation and gingivitis, as well as masking bad breath. These contain substances such as chlorhexidine, cetylpyridinium chloride or alcohol with aromatic agents such as cineole and thymol.

Liquids on the market for freshening the breath often include a claim about plaque. They belong to a group of products that are excluded from the *Therapeutic Goods Act* 1989 by Order. And because they are no longer therapeutic goods, they are not subject to the Act. They fulfil the definition of cosmetic products and have to be labelled accordingly. Formulations of these kinds of products show how fine the borderline can be. Consider the following:

- **Product No. 1.** This contained 0.05% cetylpyridinium chloride. The label states: “a clinically proven ingredient inhibits plaque formation. Fights dental plaque; cleans and freshens your mouth”.
- **Product No. 2.** This also contained 0.05% cetylpyridinium chloride. The main label had the prominent heading: “Antibacterial” in red capital letters enclosed in a red frame against a white background (in the manner of the former signal headings for scheduled poisons). The label stated: “Germ killing. Helps reduce dental plaque. Soothes inflamed or infected tissue in the throat and mouth including discomfort following dental treatment”.
- **Product No. 3** contained chlorhexidine and alcohol. The claims were similar to those in Product No. 2
- **Product No. 4** contained triclosan and its claims were limited to freshening the breath and inhibiting plaque formation. It is similar to Product No. 1.

Products 2 and 3 are registered therapeutic goods and each is fully evaluated for quality, safety and efficacy. Products 1 and 4 are not therapeutic goods. They are not evaluated in any way at all although the ingredients will have been assessed by the NICNAS or the TGA.

A sponsor therefore can decide on how to position two identical formulations for oral use that contain an antiseptic. Under Australian legislation, if the sponsor wishes to restrict the representations to breath freshening and/or inhibiting plaque formation, the final product is Excluded from the *Therapeutic Goods Act* 1989. If the sponsor wishes to extend the representations to gingivitis and other conditions, he must be prepared to provide convincing clinical and scientific evidence to support the claimed efficacy as well as meeting quality standards and safety requirements.

At first sight, there might seem to be an inconsistency between the way this Report proposes how these articles are treated compared with antibacterial handwashes. Whereas mouthwashes (for freshening the breath or reducing plaque and no more) that contain an antiseptic are cosmetic products, the antiseptic in them fills one or more useful purposes, i.e. combating offensive breath and inhibiting plaque formation. In the case of antibacterial handwashes intended for general and routine domestic use as a soap substitute, the presence of the antiseptic has no legitimate therapeutic or hygiene role and may be, in public health terms, deleterious.

Fluoride salts

Fluoride salts have undergone many variations in the controls placed on them. Until the early 1960s, they were available only on prescription. For example, the Victorian *Poisons Act 1958* (Vic) restricted fluorides of metals (including ammonium fluoride) and their solutions, preparations and admixtures intended for ingestion to prescription. There were no limits on the number of times the prescription could be repeated. Those fluoride preparations that were simply mouth washes and expelled were classified under another schedule that referred to salts of hydrofluoric acid; these had to be labelled “Poisonous – Not to be taken”. In 1963, the restriction was lifted, placing fluorides for internal use – essentially sodium fluoride tablets 2.2 mg - in Schedule 2 (Pharmacy Medicine). At a time when fluoride was proposed as a prophylaxis for reducing the incidence of dental caries, many exemptions were introduced and the controls on fluorides in the Standard for the Uniform Scheduling of Drugs and Poisons continue to evolve.

In Australia, the SUSDP places fluorides for human use in Schedule 4 (Prescription Only Medicine) but there are many exceptions. Amendments made in 2004 have resulted in the following entry:

FLUORIDES in preparations for human use **except:**

- a) when included in Schedule 2 or 3;
- b) pastes, powders or gels for the cleaning of teeth, containing 1000 mg/kg or less of fluoride ion;
- c) other dental hygiene products containing 220 mg/kg or 220 mg/L or less of fluoride ion, in packs containing not more than 120 mg total fluoride, fitted with a child-resistant closure and labelled with warnings to the following effect:
 - (i) Do not swallow; and
 - (ii) Do not use [this product/name of product] in children six years of age or less; or
- d) in other preparations containing 15 mg/kg or 15 mg/L or less of fluoride ion.

Unscheduled preparations for toiletry or cosmetic purposes are excluded from the operation of the *Therapeutic Goods Act 1989* provided claims beyond breath freshening and prevention of caries are not made.

The EU Cosmetic Directive includes fluoride salts in oral hygiene products provided the concentration of total fluorine does not exceed 0.15%, a concentration seven times higher than permitted in Australia in order to be exempted from the poisons schedules in respect of dental hygiene products.

In New Zealand, the inclusion of fluoride in a formulation such as a mouthwash that claims to reduce plaque formation, would require that product to be classed as either a related product or a medicine depending on the fluoride content i.e. if less than 100 p.p.m., the product is a related product but if more than 100 p.p.m., it is a Pharmacy Medicine. The fluoride content, not the presence of an antibacterial agent, is the determining factor under the present New Zealand system. The presence of any fluoride therefore brings a product within the scope of the *Medicines Act 1981*.

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

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4.7. OTHER BORDERLINE PRODUCTS

Personal lubricants

Personal lubricants are water-miscible gels. There are no active ingredients as it is the formulation in its entirety that makes for its usefulness. The definition of “therapeutic use” does not accommodate this class of product unless a claim is made for a therapeutic purpose. In some applications, the lubricant may be used as a moisturiser while in others, it is used for sexual purposes. In the former, it would be a cosmetic (provided there were no therapeutic claims such as vaginal dryness); for the latter, the product is neither a therapeutic good nor a cosmetic, as defined.

An identically formulated lubricating gel could therefore be a therapeutic good, a cosmetic or neither. It all depends on the purpose of the product. It is possible that the label, any leaflets or advertising material may refer to more than one purpose. If so, the appropriate legislation, if any, prevails. Thus a gel that is intended for use by a doctor in the course of an internal examination could well be regarded as a therapeutic good. The same product might be mentioned for non-therapeutic purposes in the media or the Internet.

Traditional use may also influence how a lubricant is classified. If a lubricant has been used professionally for many years within a medical setting, then its position in the market could be reasonably regarded as therapeutic, even if there is no specific mention of internal examinations and the like.

That lubricants are medical devices, because they are used during certain medical procedures, is supported in section 41BD(1)(iii) of the *Therapeutic Goods Act 1989*:

41BD What is a medical device

1. A medical device is:
 - a) any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:
 - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
 - (iii) investigation, replacement or modification of the anatomy or of a physiological process;
 - (iv) control of conception;and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or
 - b) an accessory to such an instrument, apparatus, appliance, material or other article.

Note: Declarations under subsection (3) exclude articles from the scope of this definition. Declarations under section 7 can also have this effect: see subsection 7(4).

2. For the purposes of paragraph (1)(a), the purpose for which an article is to be used is to be ascertained from the information supplied, by the person under whose name the article is or is to be supplied, on or in any one or more of the following:
 - a) the labelling on the article;
 - b) the instructions for using the article;
 - c) any advertising material relating to the article.
3. The Secretary may, by order published in the *Gazette*, declare that a particular instrument, apparatus, appliance, material or other article, or that a particular class of instruments, apparatus, appliances, materials or other articles, are not, for the purposes of this Act, medical devices.

Note: A declaration under this section does not stop articles from being therapeutic goods.

4. A declaration under this section takes effect on the day on which the declaration is published in the *Gazette* or on such later day as is specified in the order.

This is a further example of the kind of product where the sponsor can determine its position in the market by different representations, as adverted to in sub-section (2) (above). Thus, a personal lubricant whose label, packaging and advertising does not relate to therapeutic use as defined is outside the Act; in other words, it is not a device (as defined above) or a therapeutic good; and if it is not a therapeutic good in the first place, it cannot be regarded as a medical device.

A personal lubricant that is not captured directly by s.41(BD)(1)(a) might be captured under s.41(BD)(1)(b) in that it is used as an accessory to an article used for the control of conception, such as rubber condoms. One well-known brand that was examined fell into the latter category and accordingly is subject to the relevant provisions of the *Therapeutic Goods Act 1989*.

Despite the sub-section, it is still possible for a personal lubricant to escape both paragraph (a) and paragraph (b). A manufacturer might not refer to use of the product with condoms but might state that it could be used in association with sex toys and non-therapeutic appliances.

Products of this kind come into contact with mucous membrane and if the membrane is damaged and is exposed to a lubricant whose composition, physical characteristics or method or conditions of manufacture pose a risk to the user, the Report considers that the public interest would be best served by bringing all of these products within the ambit of therapeutic products controls.

To place the matter beyond doubt, personal lubricants, irrespective of any representations that are or are not made, should be declared to be therapeutic products in a manner corresponding to section 7 of the *Therapeutic Goods Act 1989*.

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.

Hand wipes

These are moistened paper towels that are used where soap and running water are not always available, such as in a motor car. Others commonly used are baby wipes. Some contain an antibacterial agent. There may be circumstances where the inclusion of an antibacterial agent is justified but it is hard to think of any, especially when the exposure time is so short. An exception might be toilet seats but this is a surface use and hence outside the scope the Report.

Hand wipes that contain an antibacterial agent and make antibacterial claims should be regulated in the same way as antibacterial skin washes (see Recommendation 5B).

Blemish sticks

“Blemish sticks” are products that are presented in the form of a pencil, a sponge-tipped pen or a ball-point pen. The contents may be solids, semi-solids or liquids. They are intended to be applied to specific blemishes rather than to larger surface areas. At first sight, they have the characteristics of a cosmetic product. Examination of their compositions shows that as well as tinting substances to camouflage blemishes, they may also contain substances such as salicylic acid and glycollic acid (HOCH_2COOH) as do many cosmetic products, as mentioned in Chapter 3, *Acne washes*.

When the labels and package inserts are read, some products appear to “cross the border” from generally cosmetic claims into those that are therapeutic. This is yet another example of a class of goods where the manufacturer can make a choice on the positioning of a particular product. The following are examples of the goods in question.

- **Product No. 1** contained melaleuca oil cited and quantified as the active agent. It is included in the ARTG as a Listed Good. All ingredients were disclosed on the label.
- **Product No. 2** was described as an “anti spot pen”. These statements appeared on the primary pack:
 - “active astringent to help dry out the imperfection”. (Hamamelis is in formula).
 - “salicylic acid that works to deeply treat and clear pores where the imperfection has formed”.

Some of the words go beyond those found in the definition of “cosmetic product”; “treat” and “imperfection” being instances. An imperfection may be due to acne or something else but in the context of the whole sentence and given that salicylic acid is a keratolytic, it would be difficult to conclude that the product was for other than acne, and not merely to cover up the lesion.

- **Product No. 3** made no direct or indirect therapeutic claims and its use centred on unblocking the pores.
- **Product No. 4**, marketed under the brand name “Skin Doctors Zit Zapper” described itself as an “intensive pimple treatment”. It claimed to “calm inflammation”, “cleanse out the affected area”, “dry out spot” and to “deeply exfoliate and unclog skin pores”. The ingredients included zinc sulphate, salicylic acid, glycolic acid, camphor, hamamelis and menthol. The salicylic acid’s role was to “calm inflammation”.

Product No. 1 is a Listed therapeutic good; Product No. 3’s claims appear to be cosmetic. Product No. 2 is probably a therapeutic good purporting to be a cosmetic but with a modification of claims in accordance with the NCCTG’s *Cosmetic Claims Guidelines* would be a cosmetic product. Product No. 4, having regard to both composition and text is, in this Report’s view, a therapeutic good. Its title, the name of the range, mention of inflammation and pimple treatment are all characteristics that point to a primary therapeutic, rather than a mere cosmetic role. What is its purpose on the market? The answer is on the label; namely, to treat pimples.

No recommendations need arise from this class of goods as existing laws and guidelines make the boundaries reasonably clear and enforcement is a matter for the relevant authorities.

APPENDIX 1 – DEFINITIONS

Australia



Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991, regulation 3

cosmetic product is a substance or preparation intended for placement in contact with any external part of the human body, including the mucous membranes of the oral cavity, and the teeth, with a view to:

- altering the odours of the body; or
- changing its appearance; or
- cleansing it; or
- maintaining it in good condition; or
- perfuming it; or
- protecting it.

[Note: The *Therapeutic Goods Act 1989* does not define the terms “cosmetic” or “cosmetic product” but the National Co-ordinating Committee on Therapeutic Goods adopted the Trade Practices definition for the purposes of its document, *Cosmetic claims guidelines*.]

Industrial Chemicals (Notification and Assessment) Act 1989, Section 5

cosmetic means a product applied to a person’s body for the purpose of its cleansing or care, colouring it, influencing its smell, or otherwise changing its appearance or smell, without affecting its structure or function.

[Note: The Report understands that this definition is to be amended to use the same words as those in the Trade Practices (Consumer Product Information Standards) (Cosmetics) Regulations 1991 (above). The uniform definition would be similar to, but not the same as that used in the UK/EU (below)].

Therapeutic Goods Act 1989, Section 3

medicine means:

- a) therapeutic goods that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human or animal; and
- b) any other therapeutic goods declared by the Secretary, for the purpose of the definition of therapeutic device, not to be therapeutic devices.

therapeutic goods means goods:

- a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
 - (i) for therapeutic use; or
 - (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
 - (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
- b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);

and includes goods declared to be therapeutic goods under an order in force under section 7, but does not include:
- c) goods declared not to be therapeutic goods under an order in force under section 7; or
- d) goods in respect of which such an order is in force, being an order that declares the goods not be therapeutic goods when used, advertised, or presented for supply in that way; or
- e) goods for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the *Australian New Zealand Food Authority Act 1991*; or
- f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

therapeutic use means use in or in connection with:

- a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or
- b) influencing, inhibiting or modifying a physiological process in persons or animals; or
- c) testing the susceptibility of persons or animals to a disease or ailment; or
- d) influencing, controlling or preventing conception in persons; or
- e) testing for pregnancy in persons; or
- f) the replacement or modification of parts of the anatomy in persons or animals.

Canada



Food and Drugs Act, Section 2

Cosmetic includes any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth, and includes deodorants and perfumes.

Drug includes any substance or mixture of substances manufactured, sold or represented for use in

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- b) restoring, correcting or modifying organic functions in human beings or animals, or
- c) disinfection in premises in which food is manufactured, prepared or kept.

New Zealand



Medicines Act 1981, Section 2

Cosmetic means any substance or mixture of substances used or represented for use for the purpose of beautifying, improving, protecting, altering, or cleansing the hair, skin, or complexion of human beings; and includes –

- a) Any perfume:
- b) Any deodorant:
- c) Any insect repellent:
- d) Any dusting powder:

Related product and *new related product* have the same meanings assigned to those terms by section 94 of this Act.

Section 3(1)

medicine means any substance or article, other than a medical device, that is manufactured, imported, sold, or supplied wholly or principally –

- a) For administering to one or more human beings for a therapeutic purpose; or

- b) For use as an ingredient in the preparation of any substance or article that is to be administered to one or more human beings for a therapeutic purpose, where it is so used
 - (i) In a pharmacy or a hospital; or
 - (ii) By a practitioner; or
 - (iii) In the course of any business that consists of or includes the retail sale, or the supply in circumstances corresponding to retail sale, of herbal remedies; or
- c) For use as a pregnancy test.

Section 4

therapeutic purpose means –

- a) Treating or preventing disease; or
- b) Diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition; or
- c) Effecting contraception; or
- d) Inducing anaesthesia; or
- e) Altering the shape, structure, size, or weight of the human body; or
- f) Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way; or
- g) Cleaning, soaking, or lubricating contact lenses.

Section 94

1. *related product* means any cosmetic or dentifrice or food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose; but does not include-
 - a) Any medicine;
 - b) Any substance or article of a kind or belonging to a class that is declared by regulations made under this Act to be a kind or class of substance or article that is not a related product for the purposes of this Act.
2. *new related product* means a related product that-

- a) Is not identical with any related product that could have been sold lawfully immediately before the commencement of this Part of this Act for the same therapeutic purpose as that claimed in respect of the new product; or
- b) Is of a kind that has been referred to the Minister under section 24(5) of this Act (as applied to related products by section 96(3) of this Act).

United Kingdom/European Union



Cosmetic Products (Safety) Regulations 2003, regulation 3

Cosmetic product means any substance or preparation intended to be placed in contact with any part of the external surfaces of the human body (that is to say, the epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition and correcting body odours except where such cleaning, perfuming, protecting, changing, keeping or correcting is wholly for the purpose of treating or preventing disease.

Cosmetic product intended to come into contact with the mucous membranes means a cosmetic product intended to be applied in the vicinity of the eyes, on the lips, in the oral cavity or to the external genital organs, and does not include any cosmetic product which is intended to come into only brief contact with the skin.

Article 1 or Directive 65/65 EEC

Medicine is any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal product.

United States of America



Food, Drug, and Cosmetic Act

Section 201(i)

Cosmetics means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles: except that such term shall not include soap.

Section 201(g)

Drugs means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any articles specified in clause (A), (B), or (C).

Dictionaries

Concise Oxford Dictionary

cosmetic 1. *a.* intended to beautify hair, skin, or complexion etc.; intended to improve appearances". 2. *n.* cosmetic substance.

Merriam-Webster Dictionary

cosmetic 1. of, relating to, or making for beauty esp. of the complexion: beautifying; 2. done or made for the sake of a: appearance: b: decorative, ornamental c: not substantive: superficial; 3. visually appealing.

APPENDIX 2 – NICNAS LOW REGULATORY CONCERN CHEMICALS (LRCC) REFORM

In announcing the Government response to the Chemicals and Plastics Action Agenda, the Australian Government committed itself to, amongst other things, reducing unnecessary regulation. In particular, the Government gave a commitment to continuing to work with industry to ensure the most efficient regulatory system is in place for industrial chemicals (including cosmetics), that is, a system that does not inhibit the introduction of new and safer chemicals. The Government agreed to consider and develop options for access to adequately assessed and/or tested chemicals presenting low regulatory concern.

In November 2002, the former Parliamentary Secretary to the Minister for Health and Ageing, the Hon Trish Worth, MP, established a Task Force to investigate the reform of the regulation of industrial chemicals of low regulatory concern. The LRCC Task Force, chaired by Dr Margaret Hartley, Director, NICNAS, was made up of individuals from government, industry and the community to oversee the LRCC initiative and provide expert input as required. Technical working groups were established with members from industry, government and the community working together to explore options for LRCC and investigate the feasibility of implementation in Australia. Extensive consultation was undertaken with the industry and community sectors. Public comment was sought on the *Low Regulatory Concern Chemicals Public Discussion Paper* and its supplementary paper, *LRCC Draft Regulation Impact Assessments for Reform Options*.

Acknowledging that cosmetics present regulatory challenges that are different to other industrial chemicals, cosmetic were considered separately under the LRCC. Many cosmetic products are imported as fully formulated and packed products that have a safe history of sales around the world. The cosmetic industry claims that because of the competitive nature of the industry, companies take responsible steps to ensure product safety. Industry has also advised that an unsafe product would destroy a brand and have significant impact on a company. Regulation of cosmetic chemicals in Australia is one of the most stringent in the world. Further specific safeguards are in place for certain classes of cosmetic chemicals. However, some areas for reform were identified for which consumer safety can still be maintained whilst reducing some elements of regulatory requirements.

While it is possible that several recommendations in the LRCC report will be applicable to chemicals introduced into Australia in cosmetic products, the following recommendations apply exclusively to cosmetics:

Recommendation 5.1

Introduce audited self-assessment for all cosmetic ingredients with annual volumes of 10 kg per 12 months or less with the notifier to undertake risk assessment and (a) determine that the chemical does not pose an undue risk to human health and the environment; and (b) that it meets existing safeguards. Notifier to retain this information that will be subject to NICNAS compliance audits and “spot-checks” and an annual report to NICNAS.

Safeguards for cosmetics will continue to include that the chemical must not be used in the cosmetic as:

- *a preservative; or*
- *a colouring agent; or*
- *an ultraviolet filter;*
- *the chemical must not be prohibited or restricted for use as a cosmetic, or for use in cosmetics in the EU or USA under cosmetic legislation;*
- *the chemical must comply with all relevant Commonwealth/state/ territory regulations; and*
- *if the chemical is present in the cosmetic at a concentration of 1% or more, it must be safe for use by high-risk groups consistent with its anticipated use pattern.*

Recommendation 5.2

Require advice of introduction for low hazardous chemicals for cosmetic use of more than 10 kg and up to 100 kg per 12 months; similar to the current less than 10 kg exemption notice with self-assessment statements, declaration of compliance with current safeguards and submission of product label and MSDS. An audited self-assessment will be undertaken and an advice issued by NICNAS as an outcome.

Recommendation 5.3

To amend the definition of cosmetics currently used in the Act to that used in the Trade Practices Act 1974 thus improving consistency in the Government's regulatory approach to cosmetics.

Recommendation 5.4

Recognising that negotiations are ongoing between industry and the TGA, the LRCC Task Force recommends that the Parliamentary Secretary asks NICNAS and TGA to examine the reform options for addressing the interface issues dealing with:

- *antiperspirants,*
- *mass market anti-dandruff shampoos,*
- *moisturisers with SPF,*
- *antibacterial skin washes; and*
- *anti-acne skin cleansers.*

The main trigger for the review of products at the cosmetic-therapeutic interface was Recommendation 5.4 of the LRCC report (see above).