Direct Selling Association
of
New Zealand Inc

Submission to National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Therapeutic Goods Administration (TGA)

On

Review of Cosmetic – Therapeutic Interface

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The Direct Selling Association of New Zealand is available to clarify any comment offered in this submission document.

Background

The Direct Selling Association of New Zealand Inc. (DSANZ) is a membership organisation representing companies within the broad description of the association name.

The present membership consists of Direct Sellers including cosmetic manufacturers and/or distributors of both cosmetic and other products within New Zealand and by value around 21% of the market.
Membership is voluntary however it is governed by a Code of Practice governing conduct and many of our members involved in cosmetic sales are also members of the Cosmetic Toiletry and Fragrance Association.

Currently the membership totals 38 members and included supplier members.

The DSANZ works in close cooperation with groups such as the CTFA and the Employers and Manufacturers Association.
The DSANZ membership has products that fall within the definition of therapeutic products in Australia and all are in the category of low risk to consumers and are topical of nature.
Our members generally do not supply toothpaste or oral hygiene products which are governed in New Zealand under the Medicines Act.

Our membership is generally familiar with the TGA and the Australian regime with many of our members also operating in Australia and members of the DSAA.

We do have some significant cosmetic suppliers who are not members of the CTFA and one who manufacturers for both markets in New Zealand.

SUMMARY STATEMENT

The DSA New Zealand does not accept that cosmetics should be regulated under the Joint Therapeutic Agency but should be governed for New Zealand under the Hazardous Substances and New Organisms (HSNO) Act. We support all cosmetics being regulated under the HSNO Act including sunscreens and those products that have previously been deemed related products under the New Zealand Medicines Act 1981.

Those products stated as being cosmetics under the Medicines Act 1981 should be treated as "Cosmetics" under HSNO.

We believe that accepting international best practice is essential for GMP and testing standards and, that such standards, as those applicable in Europe and the US should also be acceptable for establishing generic controls for products sold in New Zealand.

The DSANZ New Zealand supports initiatives by the Australian industry to remove cosmetics from coverage under the Therapeutics regime and argues that the equivalent safety record under New Zealand's light handed regulatory regime provides evidence that the Australian regime is unnecessary, costly and holds back innovation of newer and safer products into the market for consumers benefit.
The control of SPF labelling under the Australian Trade Practices Act and the New Zealand HSNO and Fair Trading Acts provides sufficient enforcement to ensure that labelling is correct.

New Zealand has less levels of skin cancer risk to Australia and some would argue more with closer proximity to the ozone layer hole; however we have continued to govern sunscreens as Cosmetics and apply a light handed regulatory regime with positive benefits to consumers in choice and protection and no negative public health issues.

Good sun protection is not just about sunscreens but a range of actions including cover, education and clothing. Sunscreen provides the final barrier and it is important to provide

The DSANZ supports the CTFA New Zealand Submission on product specific issues and does not choose to restate these issues separately.

Submission

The Current Australian Position

The current regulation of Sunscreens in Australia requires ingredient approval, GMP Auditing, labelling and prescriptive acceptable claims and this is quite unacceptable from a New Zealand industry perspective. This forces at least one of our members to contract manufacture their products whether moisturisers containing SPF or full sunscreen products.

We believe that there is no scientific, public health and safety argument or commercial basis for the continued regulation that can reasonably be substantiated of justified in New Zealand with its long experience of no adverse effects from marketing and advertising self regulation.

Cosmetics are not considered as medicines anywhere in the world. Where there are borderline categories that need to be individually defined in America and Canada controls arose out of the 1938 Food Drug and Cosmetics Act in the USA with the monograph system for borderline products. In Europe a more modern system was implemented in 1976 with a Cosmetics Directive using positive and negative lists to controls ingredients.
Australia is the most restrictive with pre-clearance through a licensing and manufacturing auditing system and this is now no longer best practice. The uneventful history of sunscreen products that we have in New Zealand leads us to believe that Australia has placed undue emphasis on its regulatory process.

Regardless of the recommendations made in this review, we believe there is no basis for continuation of the current Australian regulatory imposts for sunscreens or mandatory requirements for other cosmetic products claims, labelling and GMP under the Therapeutic Goods Authority.

The Changed Recommended.

We do not accept that the recommendations should in any way be accepted or carried forward to the Joint Agency.

The DSANZ New Zealand supports Trans-Tasman harmonisation to ensure both countries get the best possible outcomes from a joint regulatory environment however we do not see the recommendations made in this review as achieving this.
The recommendations are one sided and detrimental to New Zealand industry and consumer choice with only one area of benefit able to be determined for New Zealand.

THE SCIENCE AND THE REGULATION

The DSANZ New Zealand makes the following points and elaborates on these in the course of this submission.

1. There is no "Regulatory Impact Statement" undertaken with this review
2. There is no diminution of public health and safety in New Zealand in the absence of a TGA based regime that would support this regime becoming part of the Joint Therapeutic Agency
3. There is a lack of scientific basis in the recommendations given
4. The impact on Trans-Tasman trade has not been considered
5. These recommendations are not representative of the lowest regulatory application
6. Regulation should be related to the degree of risk – for example what is the risk of the product not working?
7. The Joint Trans-Tasman Agency if it is to be a worlds best agency should be looking to pick up the European Union best practice and not invent its own

Regulatory Impact Statement

There is nothing in the review document that takes into account the impact on the industry and in particular that of the New Zealand industry should these recommendations form the basis of the Joint Therapeutic Agency requirements for the cosmetic products being covered.

The first step should be to undertake this work and since this is purported to be a Trans-Tasman document look at all the impacts on both sides of the Tasman.

The cost to cosmetic companies in New Zealand would be extreme with the loss of product choice and the ability to bring better products to market

Diminution of Public Health and Safety in New Zealand

The key issue ignored in this report is that fact that there is no diminution of public health and safety in New Zealand and therefore to advocate regulations that are intended to reduce risk to the public, can not be substantiated.

If there are areas where the health and safety of New Zealanders is less due to the lack of such regulation, then perhaps the argument could be made for some regulation although it is doubtable that the level of regulation currently applied in Australia or even the reduced level of regulation proposed in the report would be necessary.

We would argue "where are the harmed consumers or the misled consumers in New Zealand?"

On the last question of misleading consumers, both countries have trade practices legislation (Fair Trading Act for New Zealand) and that is the right and proper place for such controls. This need not be the concern of a separate agency.

Lack of Scientific Basis to Recommendations

If the recommendations are based on science then they would make similar recommendations based on risk for all areas. How is toothpaste, an oral use cosmetic any less risk than a Sunscreen which is topically applied?

The recommendations must be consistent at least and therefore those contained in this report are more opinion than science and consistency not demonstrated.

Impact on Trans-Tasman Trade

While there may be some argument that the regulation under a joint agency will make it simpler for compliance for those involved in Trans-Tasman Trade, we believe there is no benefit involved for New Zealand.
Those companies already involved in supplying products to Australia, comply with the existing regulatory environment by either contracting out work to approved third parties where their plants can not meet the strict GMP Audit requirements or have already upgraded to meet those requirements where volumes justify such upgrades. Such costs are considered unreasonable and excessive for cosmetic products. You should note that since 1982 the Division of Clinical Services of the New Zealand Department of Health (now Medsafe) issued a Code of GMP for the Manufacture and Packaging of Cosmetics, commonly called the Blue Book. This code was endorsed by the CTFA New Zealand and the Department of Health has used this Code as the basis of inspecting factories making cosmetics and toiletries. The review did not pick this Code and New Zealand's industries compliance to it.

There are, however a range of products that are sold in New Zealand that are not supplied in Australia simply because of the current TGA sunscreen requirements and mandatory claims or approval requirements. These include a wider range of sunscreen products and anti-bacterial soaps. There has been no assessment of the impact of imposing these proposals on New Zealand under the Joint Therapeutics Agency against the purported benefits
This impact study must be assessed whether independently or as part of the regulatory impact study.

Recommendations not representative of the lowest regulatory application

Where regulation is required, it must be based on COAG principles and the least regulatory intervention required assessed, producing the desired outcomes. The recommendations in the review are not based on this and are instead some reductions on existing regulatory controls based on continuing and maintaining the established regime and the present overall structure.

If COAG was applied to the Cosmetics in this review then all highlighted in the review would be treated the same as other countries treat them under "Cosmetics" and nothing more.
The New Zealand Cosmetic regime being established under HSNO picks up worlds best practice and recognises compliance to appropriate regimes as being compliance for New Zealand. This includes the European Unions Cosmetic Directive where all the interface products of this review are not only controlled as Cosmetics, but GMP is appropriate to the Cosmetic industry and not to the Pharmaceutical industry.

Acceptance of such international standards is imperative in the global marketplace where products are manufactured for international markets and not solely for one small market such as New Zealand or Australia. Even the combined size of both markets barely rates notice against the scale of markets such as the European Union or the USA and to ignore

them damages competitive forces from operating and ensuring our domestic producers are able to match the worlds best.

Regulation should be related to risk

Fundamentally this comes back to risk and regulation to the level of risk involved. The risk of an anti-acne cream/cleanser not working is the acne will not reduce or disappear and the purchaser of the product will not buy that product again. If that were the case then the Fair Trading Act in New Zealand and the Trade Practices Act in Australia is quite capable of dealing with misleading the consumer and the penalties are equally adequate.

All ingredients in Cosmetics are risk assessed by authorities in Europe, America and through NICNAS in Australia and HSNO in New Zealand and the excipients in Sunscreen products fall into this category. Ie they are already safely used and have been risk assessed by several levels of authority. Therefore why do we require under the TGA/Joint Agency, a full reassessment when a particular Herbal Extract or Fragrance is added when the properties of the product's SPF has not changed and the same extract or fragrance may have been widely used elsewhere in the cosmetics products and assessed already by NICNAS or the ERMA.

To regulate such products other than as a "Cosmetic" is not managing risk, it is far more than this! It does not improve public health and safety, it just adds costs. Excessive regulation restricts the availability of new products that may perform better, but are just not cost effective to introduce to the market under the proposed regime.

Joint Therapeutic Agency and Worlds Best Practice

The world's best practice is widely acknowledged as being the European Union under the Cosmetic Directive. There is equally good practice available from the US under the monographs and to ignore these agencies and regimes in favour of a stand alone agency even for a limited number of cosmetic products, is not adopting worlds best practice but applying a non tariff barrier and anti-competitive rules for entry into the Australian market and through the Joint Agency the New Zealand market.

There should be an automatic acceptance that products produced under these markets rules with it noted that New Zealand has its own Cosmetics GMP and Packaging requirements approved 23 years ago by the Department of Health and operated successfully in New Zealand over this time. The EU Industry GMP Guidelines and their forthcoming ISO standard on Cosmetics – GMP Guideline on Good Manufacturing Practice are similar.

The revised New Zealand industry Cosmetic Code accepts existing and proposed GMP used in Europe, recognises US Monographs as acceptable and is designed to align to provide domestic manufacturers with an alternate tool to comply not only with HSNO but for supply to those markets.
World's best practice clearly demonstrates that a full approval regime for cosmetic interface products is both unnecessary and over regulation regardless of perceived therapeutic benefits.

At most, controls over active ingredients use aligned to the Cosmetic Directive should be considered under HSNO for New Zealand or NICNAS for Australia "for Cosmetic use"

where appropriate, but we do not accept that these products/ingredients are required to be controlled under the Joint Agency as Therapeutics.