SUBMISSION

by

EMPLOYERS AND MANUFACTURERS' ASSOCIATION (N) INC.

to the

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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1. BACKGROUND

This submission is made by the Employers and Manufacturers Association (N) Inc. (EMA) The EMA is made up of approximately 7500 member companies covering the New Zealand region north of Taupo. This membership includes approximately 1500 manufacturers ranging from large to SME.

Within our membership there are a significant number of companies involved in the manufacture supply, distribution and use of products on a Trans-Tasman basis.

The EMA includes in its advocacy role a keen interest in trade (export and domestic issues) and that of compliance costs for our members both within the New Zealand market and under international agreements such as CER and the rules that apply within such agreements.
The EMA has focused its submission on the core issues of the review rather than the details related to products which are amply represented by associate groups such as the CTFA New Zealand.

The EMA has participated with Medsafe through the CTFA and DSA in meetings to assist develop agreement on what may be acceptable under any Joint Agency arrangement.

2. CONTACT

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SUMMARY STATEMENT

The EMA supports initiatives by the Australian cosmetic 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, is unduly expensive, constrains innovation by way of development of new and safer products for the market, all at the expense of consumers.
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 recorded levels of skin cancer risk than Australia and with closer proximity to the ozone layer hole, however New Zealand has applied a light handed regulatory regime with positive benefits to consumers in choice and protection with clearly no detriment to public health and safety.

We therefore contest the argument that sunscreen products require any additional regulation in New Zealand and believe that nothing in the draft report supports applying the Australian regime either in its current form or with any changes that may arise from this report, supports such regulation.

The report lacks scientific cohesion, consistency and evidence for the recommendations made.

There needs to be considerable work done in a number of areas before this document can be considered to provide credible arguments for any of the recommendations.

We do recognise that some of the recommendations would be of immediate benefit to both domestic Australian business and to some New Zealand exporters if applied and therefore fully support those recommendations being implemented as soon as possible for Australia. However, we do not accept that these recommendations should be carried forward to the proposed Joint Agency without further consideration including economic impact statements and scientific evidence that the regulatory proposals are appropriate for the actual levels of risk.

Submission by the EMA

Principles of Review

The EMA argued in our original submission the need to ensure that the review provide the principles for setting the relationship of cosmetic products to that of therapeutic products with the lowest possible regulation appropriate to risk.

This review draft does not achieve this principle and we consider that the assurances that the lowest level of regulation appropriate in either country has not been considered in this review and instead a modification of the status quo or TGA regime has been endorsed.

It is therefore inapropriate to bring this review forward to any Joint Agency on the basis of being reflective of meeting the underlying principles.

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.

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 control 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 Changes Recommended.

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

The EMA 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 EMA 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 at the European Union or USA for 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 the 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, cannot 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 doubtful 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 with consistency not demonstrated.

Impact on Trans-Tasman Trade

While there may be some argument that regulation under a joint agency will make for simpler 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 New Zealand industry 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 for domestic use. 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.

If COAG is being appropriately applied then the costly mandatory auditing of manufacture to GMP would be unnecessary and a declaration system the most that would be required to establish compliance. Even this level of compliance is seen as more than necessary for the risk being addressed in these products.

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.

If a sunscreen excipient is risky then virtually every cosmetic product has the same degree of risk since many of the ingredients are often common with the exception of those that apply to the SPF being achieved. 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 those other 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 based 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 or subject to unnecessary and costly mandatory audits to establish compliance

Public Health and Safety arguments are being used to justify regulator controls that are not warranted by the risks and the facts speak for themselves in areas of skin cancer control and the lack of public health incidents or issues when New Zealand is compared to Australia.