Address

To Australian Government
Department of Health & Ageing
Therapeutic Goods Administration
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Introduction

This is a submission in response to the Draft for Comment:

Title **Review of the regulations of products at the interface between cosmetics and therapeutic goods.**

This submission is a positioning structure for consideration of the manufacturers and their status with respect to the manufacture of LOW **RISK PRODUCTS** that may be classified either cosmetics or Listed Products by the TGA.

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Company Position. Managing Director.

Confidentiality sought. None.

The present New Zealand legislation allows a broader participation for manufacturers in the cosmetic industry to manufacture products considered, and classified by the TGA as therapeutic.

The marked difference in the cosmetic to therapeutic classification between New Zealand and Australia is distinctly presented in this draft review by the detailed information **SUNSCREEN-CONTAINING PRODUCTS (4.3).**

If the sunscreen containing products are **all** to be classified as contact topical applications with no reference to their therapeutic claims or classification then without exception they could be designated Low Risk Products.

(1 of 2)

This is demonstrated by the TGA classification of

a. Moisturiser containing Sunscreen. No statement of SPF number is a cosmetic.
b. Moisturiser containing Sunscreen stating SPF of >4. The claimed primary purpose for protecting the skin from suns harmful rays.

At the point of manufacture, products (a.) and (b.) above can be identical products and as far as manufacture is concerned are both low risk products. The physical combination of the ingredients can be identical. Because of the stated designation of the preparations use product (a.) (Moisturiser containing Sunscreen nil SPF rating) is made as a cosmetic, little if any designated quality control, no validation required.

Product (b.) the identical product at point of manufacture is a Listed Product requiring all the conforming QA and validation. It must be able to be considered a low risk product by virtue of its formulation and manufacture. It is only the legislation that differentiates these two products. Product (b.) only constitutes a risk when it fails to deliver the therapeutic claim (SPFx).

Both in New Zealand and Australia product (a.) is able to be manufactured in a non audited cosmetic plant. In Australia product (b.) is required to be manufactured in a fully audited GMP facility and standard validation requirements for ingredient and finished product are required. In New Zealand product (b.) is able to be manufactured in any cosmetic facility.

I would like to make the following recommendation.

1. Establish a category of Low Risk Products and ingredients.
   This would require a transparent evaluation of the product considering the dosage or application requirement.
   a. Would overdosing create a harmful situation for the patient or recipient i.e. exceeding the recommended dose of Vitamins?
      Exceeding the required % of Titanium Dioxide in a sunscreen.
   b. Would under dosing deprive the recipient of expected protection or create a health hazard i.e. less than the required dose of a hormone in an oral contraceptive.
      20% less quaternary antibacterial in a topical skin wash.
   c. Incompatibilities: Physical in compounding and likely contra indications with other food or medication when taken or applied.
   d. Likely contact reactions i.e. topically applied plant extracts.

2. Establish a new sector for the manufacture of Low Risk Products.
   Compounds of a dosage form containing Low Risk Products or the combination of products creating a Low Risk Product.

The sector **LOW RISK THERAPEUTIC COMPOUNDS.**

The following criteria would need to be considered.

a. Suitable premises to be audited to a standard applicable to the manufacturing function being undertaken.
b. Competent management and technical staff to manufacture and quality control production.
c. Documentation required for traceability.
d. All ingredients require manufacturers Certificate of Analysis. Manufacturer to accept the stated quality of each ingredient.
e. Manufacturing procedures to be documented and checked at time of dispensing and manufacture.
f. Release of products to be passed by the manufacturer. Quality assurance to be the manufacturer's responsibility.
g. All labeling procedures to be tracked. (GMP compliant).

Validation.

No ingredient validation to be required by the manufacturer so long as

1. Ingredient manufacturer is considered reputable and to supply a C of A with each batch.
2. No final product validation required as long as all manufacturing sheets are completed and allow for traceability of all ingredients.
3. Batch numbers required on all finished products.
4. Expiry date required. Normal GMP conditions.

Conclusion.

The establishment of a classification for Low Risk Products would make the total structure from Cosmetic through to Medicines transparent and workable.

The establishment of a sector within Cosmetics, Listed, and Registered relating to the manufacture of Low Risk (Therapeutic Type) Products would clearly control and elevate this sector out of the uncontrolled cosmetic manufacturing sector. At this point in time cosmetics could be (and at times are) manufactured in domestic kitchens, bathrooms and various unsuitable locations.

- Auditing to be to a suitable level in relationship to risk. This should not be made to arduous.
- Independent validation over and above ingredient manufacturers C of A and finished product validation should not be mandatory. Full internal manufacturing documentation plus traceability would be required. Standard microbiological testing require as applicable.
- Standard labeling requirements to be implemented.

LOW RISK MANUFACTURERS ASSOCIATION.

It is my contention that an Association should be established to encompass manufacturing of Low Risk (Therapeutic) Products.

It should be mandatory that all manufacturers of Low Risk Products be required to be a member of the association and a suitable code of ethics be constituted. This association should have the ability to self regulate this sector of the manufacturing industry.

The Benefits of establishing this Low Risk Sector.

1. Would clearly form an interface between cosmetics and medicines. It would work towards a more regulated transition from cosmetics to medicines.
2. Would enhance the protection of the public health, safety and environmental standards. Would be consistent with the objectives of the TGA and Medsafe.
3. Establishment of this sector with a member association would be compatible with cost recovery required by government policy.
4. Would establish a more controlled sector for "Exempt Goods" (Australia) and "Excluded Goods" (Australia).
5. May clarify the difference between Cosmetics and Related Products in New Zealand.
6. Able to encompass manufacture of goods where there is little real control exerted i.e. Acne Washes (Australia). Also minimally regulated products under the Act (TGA 1989). Some anti dandruff Shampoos.
7. Will allow for small production and innovative development of fringe type Therapeutic products, so fostering an area normally unattractive to large scale manufacturing and medicine production.

Many of the large scale production facilities in New Zealand and presumably in Australia have developed from small and normally economically viable small entities.

The recognition of Low Risk (Therapeutic) Products and the establishment of a Low Risk Manufacturing Sector are required for both New Zealand and Australia.

Robin Sinclair MPS NZ. Managing Director Robin Pharmaceuticals Ltd NZ.