New Zealand Self- Medication Industry Association Inc
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Review of the regulation of products at the interface between cosmetics and therapeutic goods

Response to the Draft for Comment dated 18 March 2005

Background

The New Zealand Self Medication Industry Association Inc is the national trade association representing manufacturers, marketers and distributors of a wide range of products , generally available "over-the-counter" and mainly for use in self-medication by consumers as an integral part of the wider concept of self-care.

These industry products include non-prescription medicines, dietary supplements and other complementary healthcare products that meet New Zealand legislative requirements. Included in the product portfolio of some member companies are products that are the subject of this review.

As a condition of membership, companies must abide by the NZSMI Code of Practice including the need to meet all Good Manufacturing Practice standards applicable to manufacturing, warehousing and distribution deemed appropriate by the New Zealand regulatory authority, Medsafe.

A current membership list is attached.

Overview

The Guiding Principles for reform of the regulation of products at the cosmetic-therapeutic interface (Pp v 16 January 2005) enunciate the need "to maintain and enhance the protection of public safety". This principle is certainly one that all sectors would support. However, the issue becomes of how best this goal can be met given that originally this Review focused on consistency with objectives of a wide range of existing Australian legislation. It is also important to balance the 'public safety' aspect against unnecessary regulation which then, directly or indirectly, can restrict consumer access to products.
Subsequently, with the prospect of the Joint Agency for therapeutic products this review expanded to consider the New Zealand scenario.
It is evident that there are considerable differences, in both countries in defining what is or is not a cosmetic and the process by which ingredients for these products are considered. The specifics surrounding these issues no doubt will have been covered in detail by those directly involved in the cosmetic sector.
Due cognisance should be taken of the *least regulatory impost* currently applicable in either country in determining any future definition of whether a product is considered to be a therapeutic or a cosmetic under the Joint Agency.

As a trade association it has been part of our objectives to ensure, wherever possible, a 'level-playing field' to protect members' interests. In New Zealand, the relatively small number of NZSMI manufacturers (2) is already GMP compliant to a pharma level and we understand the cosmetics industry in New Zealand has, within their Code of Practice, a level of GMP that meets requirements appropriate for what can only be considered as 'low-risk' products.

Therefore, the issue in New Zealand is more one of promotional claims rather than any public safety concerns about quality or efficacy. There are avenues for New Zealand consumers to lay a complaint where it is clear that a product is making blatant therapeutic claims either in product promotion or by way of consumer advertising. Under the Joint Agency such claims will come under the scrutiny of the Australia New Zealand Therapeutic Products Advertising Code. Residents of New Zealand will be able to access this route or lay a complaint under the Fair Trading Act.

Whilst there are always exceptions, it has to be recognised that there is still a philosophical difference in the manner in which Australian and New Zealand regulators apply and companies accept regulatory imposts. Therefore, we would stress the paramount importance of *best international regulatory practice* and where this is not readily apparent the adoption of *minimum regulatory control to ensure quality and public safety consistent with an appropriate risk profile.*

Consumers have the right to expect that any product they purchase (particularly for personal application) has been produced to a recognised standard consistent with risk. No doubt, there will still be considerable debate as to an appropriate level at which the bar should be set.

Although there is a view that all low risk products should be subject to some form of GMP the cost, even for an abbreviated version of GMP, is still significant and hence consumers will have to expect to pay more for these products. Consumer access can be adversely affected by overly restrictive classification and/or prohibitive GMP requirements can lead to manufacturers simply ceasing to supply product.

Specific Comments

There are two product areas of greater relevance to NZSMI member companies.

(1) Sunscreen Preparations

In previous submissions linked with the proposed Joint Agency, this organization held the view that any sunscreen preparation >SPF 15 should be regarded as therapeutic. Although this view is also shared by Medsafe, it is apparent that this pragmatic view is not held by all member companies in that most of those involved in this market have multinational links and hold views that more closely reflect those of their Australian counterparts or principals.

However, irrespective of conflicting views, we consider the proposed delineation between Primary and Secondary sunscreens will only add further complication.

Firstly, the proposal is for primary sunscreens >SPF4 to be considered as therapeutic products and yet secondary sunscreens i.e. moisturisers containing a sunscreen are not classified as a therapeutic product unless they are >SPF20.
This creates a void and possibility of confusion in the minds of consumers for secondary sunscreens in the SPF4 to 20 range and creates an immediate regulatory imbalance.

There is a view that any sunscreen <SPF15 marketed as a preventative measure against sunburn and presumably skin cancer has doubtful effectiveness. Studies in Australia in 2004 confirmed that the real public health issue is one of consumer education to ensure the product is applied correctly including frequency of application.

Perhaps of greater significance is the need to accept "best international regulatory practices". Although the current AS/NZ Standard provided a much-needed Australasian standard in its time, other equally acceptable international standards should be considered to reduce the regulatory compliance cost. This current standard is considered to be a Non Tariff Barrier in that it reduces the prospect of other international product offerings.

Given the divergence of views on the public (and industry) perception of sunscreens in both countries we would support any moves to implement independent consumer research on sunscreens before any recommendations in this Draft report are either confirmed or implemented as part of any Joint Agency activities.

(2) Antibacterial Skin Washes (including Antiseptic Hand Wipes)

Again there is no consensus view given the current treatment of these as therapeutics in Australia and as toiletry/cosmetic products in New Zealand.
Member companies' views reflect that position but we see no justification for adopting the proposed overly conservative stance that these should be considered as Class II (i.e. high risk) medicines.

There needs to be consideration in greater depth of the various products that make up this category and differentiate between those that are clearly for personal, domestic, or institutional use. It should then be possible to stratify these according to risk and claimed performance.

Other Comments

The NZSMI has a dilemma in that many member companies are influenced by current Australian practice, whereas most of these categories under consideration have been considered as 'cosmetic/toiletry' products in New Zealand. As an advocate therefore of *minimum regulatory control consistent with the level of risk* we find the arguments in the Draft for Comment in support of greater control to be at times inconsistent.

Where products either make therapeutic claims or are clearly presented for a therapeutic purpose then the minimum regulatory control should apply. We fail to be convinced of the need for consideration of the Class II Medicine (high risk category) as listed under the proposed Joint Agency unless there are defined risks to public health and safety.

Ends..

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New Zealand Self-Medication Industry Association Inc.

MEMBERSHIP LIST

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3 March 2005