NEW ZEALAND MEDICAL ASSOCIATION

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Development of a Natural Health Products Bill

Thank you for the opportunity to comment on this proposed bill.

NZMA is strongly supportive of the proposal to regulate non prescription therapeutic products. Some non prescription therapeutic products have proved to be harmful in the past – or alternatively to interact negatively with certain prescription medicines, and it is important that before being placed on the market such medicines are appropriately assessed and cautions issued if necessary. The fact that the Therapeutic Products and Medicines Bill originally proposed to regulate non prescription therapeutic products was one of the key reasons we supported that bill. As we were disappointed that the Bill was not eventually passed we are pleased to see that a proposal to regulate this industry is now being considered.

"Natural Health Products"

By way of preliminary comment we question the use of the term "natural health products" in respect of non prescription therapeutic products. Putting a substance through a process to create a pill or drink, by definition, means the product is not natural. Also, many products marketed as "natural" are in fact not; for example many chinese herbal medicines contain contaminants from pesticides, and some include western drugs which have lead to serious reactions in some patients[1]. The term "natural health product" needs to be reconsidered as not only is it often untrue, "natural" is also often interpreted by the public as being "wholesome", "good" and "safe", when this is not always the case. Instead of "natural health products" we

[1] Dharmananda, S "How Clean and Pure are Chinese Herbs?" http://www.itmonline.org/arts/cleanhrb.htm

suggest that the more accurate term to use is "non prescription therapeutic products".

"Natural Health Products are Low Risk"

Secondly we are concerned with the statements in the document that *"We want the scheme to **recognise** that, in general, natural health products are **low risk**",* (Foreword) and (in Part 2, Purpose) *"It is proposed that the purpose of the legislation will be 'to provide **assurance** to consumers that natural health products are **safe**, true to claim and true to label'."* These statements assume that natural health products are much safer than the reality suggests.

There have been many problems with natural health products either reacting negatively to other prescribed drugs the patient is taking, or otherwise causing harm. For example:

- It is dangerous to overdose on vitamin A.[2]
- Some products are contraindicated in respect of prescribed drugs or conditions – E.g. products such as ginger, garlic, Vitamin E, gingko biloba and fish oil lead to an increased risk of bleeding[3]; honey is a natural health product but would be contraindicated if the patient was diabetic.

"Natural health products" are not inherently low or high risk. Where they sit on the continuum of risk depends entirely on what the product contains, for what purpose it is being used and any potential contraindications.

Labelling

We agree with the proposal that these products need to clearly label what ingredients are contained in the product and in what quantities. Consistency of manufacture, dose and quality control over both the making of the product and the supply chain, should apply to these products equally as they apply to food drugs and anything else that is ingested. Given the serious potential interactions or side effects that some products have, we also believe that the label should set these out fully. We do not think an exception should be made for non prescription therapeutic products provided by medical practitioners.

Efficacy

Evidence of efficacy of the product is essential. It is unreasonable to allow manufacturers of non prescription therapeutic products to make claims about the efficacy of products in the absence of evidence to support this. We are pleased, however, that the bill proposes to prescribe the parameters of what the product can say in its advertisement as to what it will treat. We are always concerned where a non regulated therapeutic product is said to be – say – a treatment for cancer when

[2] Lamprecht, M "Overdose of Vitamin A. Teratogenic Effects on the Fetus: 2 July 2007 http://pregnancychildbirth.suite101.com/article.cfm/overdosage_of_vitamin_a

[3] BPAC, "INR Testing April 2005 – Using INR when initiating Warfarin Therapy, Frequency of INR Testing, Why does INR Change?" http://www.bpac.org.nz/resources/campaign/other/bpac_inr_testing_2005_wv.pdf

there is no evidence to support that statement. At a minimum, statements about a product's efficacy must not breach those minimum standards set out in the Fair Trading Act 1986 and the Consumer Guarantees Act 1993.

Permitted List of Ingredients

The paper suggests that the safety of these products will be maintained by setting out a list of permitted non prescription therapeutic product ingredients. At this point we are unsure whether this proposal would be entirely satisfactory. It does not, for example, allow for the possibility that two products while safe on their own have a negative impact when combined or are otherwise contraindicated.

Advertising

In respect of advertising, while we appreciate that the regulations will set out the basic requirements for all advertisements of non prescription therapeutic products, we believe that in doing so, regard should be had to the existing ASA Therapeutic Products Advertising Code.

Cost of Scheme

Finally we note that the paper favours the administration of the regulations by the Ministry of Health as opposed to a separate regulatory authority. Regardless of the system of administration proposed, we agree that the cost of administering these regulations is substantially borne by the industry itself as is currently the case with pharmaceutical products.

We are happy to discuss any of the above points with you further should you wish.

Yours sincerely

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Chair, NZMA