



# **Natural Health Products Bill**

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## **Natural Health Products Bill**

### **About the NZMA**

The New Zealand Medical Association (NZMA) is New Zealand's largest medical organisation and has a pan professional membership. We have around 5,000 members who come from all areas of medicine including medical students, resident medical officers, general practitioners, and other specialists.

The NZMA aims to provide leadership of the medical profession, and promote:

- professional unity and values, and
- the health of all New Zealanders.

The key roles of the NZMA are:

- provide advocacy on behalf of doctors and their patients
- provide support and services to members and their practices
- publish and maintain the Code of Ethics for the profession
- publish the New Zealand Medical Journal.

### **Intent of the Bill**

The NZMA is pleased that the Government is attempting to address the issue of regulating natural health products". We have long been concerned about the array of so called "natural health products that are made available on the market, with consumers making uninformed choices based on unproven health claims and no assurance of product safety and quality.

While the proposed legislation goes some way towards providing assurance of quality and safety through mechanisms such as manufacturing licences and prohibited ingredient lists, the NZMA is of the view that the Bill fails to provide an effective evidence based system of regulation.

The primary issues are:

- all natural health products are assumed to be low risk
- there is no pre-market requirement for products to be assessed for quality, safety and efficacy
- the Bill offers no systematic testing of products. Assessments conducted by the authority will essentially be reactive and ad hoc
- the Bill is silent on the level of evidence to support health benefit claims
- the risk of some products falling outside the definition of a natural health product and remaining on the market
- the ability of the authority to remove products from the market
- the composition of the advisory committee
- the capacity and capability of the authority.

### **Are all natural products 'low risk'?**

The Bill assumes that all natural health products are low risk and therefore only require low to moderate regulation. It is of concern that there had been no debate on whether this assumption is correct. The Ministry of Health's regulatory impact statement confirms that there is little information on the adverse events resulting from the use of natural health products given that to date there has been no systematic testing or reporting requirements for adverse events.

International data would suggest however, that New Zealanders are likely to experience adverse events. Australia for example reports approximately 400 adverse events per year and 62 deaths associated with natural health products in the 10 years to 2005<sup>1</sup>. This is considered to be an underestimate of the true effects and is despite Australia operating a much more stringent regulatory system for complementary medicines than that proposed for New Zealand.

The NZMA is also concerned that the use of the term “natural health products” implies a level of safety for consumers that is misleading. The mantra that “natural” signals that the product “will do me no harm” is patently incorrect when one considers the number of naturally occurring substances that are clearly detrimental to health. In addition to these, some products are not safe for individuals to take while on other medication or treatment, due to the individual’s age or pre-existing condition. For example in regard to post surgery care garlic, ginkgo and ginseng have all been found to increase the risk of a patient bleeding while ephedra increases the risk of myocardial ischemia and stroke from tachycardia and hypertension<sup>2</sup>.

The NZMA submits that the Bill must acknowledge that **not all** natural health products are by definition low risk and that a higher level of regulation be introduced for products that are higher risk. We suggest that a two tier regulatory system be considered to provide appropriate safeguards with pre-market assessment as a requirement for higher risk products.

In determining risk and the evaluation process to be applied to natural health products, a number of factors should be taken into consideration. These include:

- the toxicity of the ingredients
- the dosage form of the product
- whether the medicine is indicated for a serious form of a disease, condition or disorder; or for the treatment, cure, management or prevention of a disease, condition or disorder
- whether the use of the product is likely to result in significant side effects, including interactions with other medicines
- whether there may be adverse effects from prolonged use or inappropriate self-medication.

The NZMA notes that a two tier system currently operates in Australia but that that model was previously rejected as too expensive for the New Zealand market. We challenge this position given recent reports<sup>3</sup> that the natural products industry in New Zealand is now worth more than \$1 billion and New Zealand Trade and Enterprise (NZTE) estimates that the New Zealand natural products industry will be worth \$5 billion by 2025<sup>4</sup>.

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<sup>1</sup> Ministry of Health Regulatory Impact Statement

<sup>2</sup> Ang-Lee, M, Moss, J and Yuan, Chuan Su, “Herbal Medicines and Perioperative Care”, JAMA, July 11 2001, vol 286, no 2 pages 208 - 216

<sup>3</sup> Sunday Star Times “Natural Products industry busts \$1 billion barrier” 22 January 2012

<sup>4</sup> <http://www.nzte.govt.nz/features-commentary/Features/World-business-trends/Pages/Natural-leaders.aspx?pageId=2>

### **Pre-market assessment**

The proposed notification system is no more than a self declaration of product ingredients and statement that the sponsor holds evidence to support any health benefit claims. This assumes a level of integrity and desire to comply with the rules that is not evident in the behaviour of the industry to date. Suppliers frequently make therapeutic claims for their products in breach of the current regulations and have rarely been held to account. In addition, from a commercial perspective the advantage of getting a product to market may far outweigh any sanction imposed by the Authority should an issue come to light at a later date.

While ideally all therapeutic products should be assessed prior to market access, the NZMA accepts that for very low risk products this is probably not required from a safety and quality aspect, assuming manufacturing standards etc are assured. However, from a consumer protection perspective those making significant health benefit claims should have that evidence examined prior to market. For higher risk products, assessment of quality, safety and efficacy must be conducted pre-market.

The absence of systematic testing, both at pre-market and at any other stage during the product lifecycle, reduces the safeguards offered by the proposed regulation to safety and efficacy assurance by exception. Notification requirements and rules around prohibited ingredients etc are likely to be adhered to by most suppliers who will make complete and accurate disclosure when notifying their products. However, it only takes either one rogue or ignorant supplier for consumers to be put at risk. As there is no mechanism to actively screen and monitor products coming onto the market the likely scenario is that an assessment and subsequent action by the Authority will only happen after an adverse event occurs and only if the event is reported. It is therefore akin to the ‘ambulance at the bottom of the cliff’ with no-one watching to see if anyone falls off the cliff.

### **Evidence to support health benefit claims**

There are two aspects to this issue. These are that the Bill does not establish any guidelines as to what level of evidence is required to support any claim that a natural health product is safe and efficacious; and secondly, that it appears that the only time evidence is required to prove this is when a complaint is lodged.

Turning first to the level of evidence required. This has not been specified and it would appear – at least at the notification stage – that a testimonial to the effect that a person has used the product and found it worked may be sufficient. In the NZMA’s view this is a significant flaw in the legislation as it means that products will now have legal backing for what they have been doing illegally for some years and can continue to market natural health products supported by unsubstantiated anecdotal claims in the knowledge that unless someone complains the sponsor cannot be held to account.

The NZMA considers that the actual standard of evidence required should be linked to the level and nature of the statement made. We note that the Australian Government’s Department of Health and Ageing Therapeutic Goods Administration has established clear guidelines in regard to what levels and kinds of claims can be made.<sup>5</sup> In essence the greater the level of the claim made, the higher the level of evidence supporting this needs to be. The

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<sup>5</sup> “Guidelines for levels and kinds of evidence to support indications and claims for non-registerable medicines including complementary medicines and other listable medicines”, V1.1 April 2011

NZMA considers that the guideline is extremely useful and would be helpful in setting out what level of evidence is required for low risk products.

Complementary medicines or natural products that are deemed to be of higher risk must be individually evaluated for quality, safety and efficacy and this process determines the claim that can be made. Efficacy is usually assessed by examining data from controlled clinical trials. However, where adequate information is available on each active ingredient, and it is well described in standard textbooks/guidelines, this could be used to support efficacy.

The Bill is also silent on product indications. While many health benefit claims will refer to general health maintenance and relief of generic symptoms, some products will be promoted as being beneficial for certain conditions. We note that the Bill excludes health benefit claims regarding relief of symptoms of any serious condition. We believe the definition of what is a serious condition is too narrow. Diabetes for example is a condition that could be described as “suitable for self management” however the risk associated with poorly managed and treated diabetes is high.

The NZMA submits that all products which claim a health benefit for a particular condition should require a minimum level of scrutiny pre-market and that the issue of contra-indications also needs to be further explored as part of this regulatory framework.

Regarding the issue of evidence only having to be presented should the Authority request it, as stated previously this significantly reduces consumer protection. While there is some likelihood that consumers will complain about any adverse effects of a particular product, it is very unlikely a consumer will complain that a natural health product has not worked. The consumer will simply make a decision not to buy the product again. This in turn means that the product continues to be sold to other unsuspecting buyers who are attracted to it by the claims that have been made.

In the NZMA’s view if the Bill is to provide natural health product sponsors with the right to make therapeutic claims then it must appropriately police that right. In our view allowing sponsors of the products to make claims based on questionable evidence, that is not verified unless a complaint is lodged, is insufficient.

We understand of course that testing the validity of the evidence at notification, rather than waiting to have a complaint lodged, is likely to have resource implications both for the Authority and the industry who will be charged fees proportionate to the activities undertaken by the Authority. However in the NZMA’s view there is no point in legislating the right to make appropriate therapeutic claims if the Bill also effectively allows sponsors the ability to make unsubstantiated or misleading claims.

### **Products that fall outside the definition of a natural health product**

The NZMA understands that the intention behind the creation of the Bill is that all therapeutic products will be covered either by the Medicines Act, the Natural Health Products Bill or the Food Act. We are however concerned that some products may be introduced, or remain on the market, and not be captured by any of the above legislation.

If a product meets the definition of a “natural health product” then the product will be regulated to the extent of the provisions ultimately passed into law and cannot be distributed in New Zealand without meeting those requirements.

Should a product fail any one of the criteria in the definition of a natural product, it would seem that the rules do not apply and the product is not a notified product. The concern therefore is that there is nothing to prevent a product that say, contains ingredients other than natural product ingredients, being marketed outside the regulations using generic health benefit claims as is the current situation.

If, as the Ministry of Health intends, the above is not an issue as no product that is ingested, inhaled, or topically applied can be sold outside the parameters of the Food Act, the Medicines Act or the Natural Health Products Bill, then ensuring that this is so comes down to a matter of monitoring and enforcement, both of which appear to be inadequately provided for under the proposed system.

### **Capacity, capability and power to act**

The NZMA is concerned that the desire to limit costs to the industry and the very large number of products to be covered by this scheme, will mean the Authority will have little scope other than to provide guidelines, passively manage an on-line registration process and undertake review, only when serious matters are brought to its attention.

With regard to product evaluation and review of claims it is disappointing that the capacity and expertise of Medsafe will not be utilised. The technical skills required to analyse and assess data for safety and efficacy is not commonplace and the decision to duplicate these activities rather than share resources is a concern.

In addition to our concerns regarding the Authority's capacity to act, the NZMA would like to see the provisions for sanction significantly strengthened. For example, while there is provision to suspend a product on the grounds of serious harm or false information, similar action cannot be taken should the Authority find that the evidence provided is insufficient to support the health benefits claimed for the product. This is a significant weakness in the powers of the Authority and it must be rectified if consumer protection is to be upheld.

The NZMA notes that the Authority will be required to establish an advisory committee to provide expert advice and that each member of the committee must have expertise in natural health products. While we support the concept of an advisory committee we would be very concerned if this committee is entirely made up of industry experts and representatives. The committee must also include independent scientific and medical expertise if it is going to be in a position to provide comprehensive advice to the Authority.

Again the NZMA thanks you for the opportunity to comment on the proposed bill, and would be pleased to appear in support of our submission.