Natural Health Products Consultation
Policy Unit
Health and Disability Systems Strategy Directorate
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NEW ZEALAND

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CONSULTATION RESPONSE

This document represents a response to the consultation paper entitled "The Development of a Natural Health Products Bill" produced by the Health and Disability Systems Strategy Directorate of the New Zealand government by the Alliance for Natural Health International.

The Alliance for Natural Health International (ANH-Intl) (www.anhinternational.org) is a not-for-profit organisation dedicated to promoting natural, biocompatible and sustainable healthcare through the use of 'good science' and 'good law'. ANH-Intl campaigns across a wide range of fields, including for freedom of choice and the use of micronutrients and herbal products in healthcare. It also operates campaigns that aim to restrict mass fluoridation of water supplies and the use of genetically modified foods. The New Zealand Health Trust, which has been at the forefront of consultations with the New Zealand government on behalf of the New Zealand natural products industry, is affiliated with ANH-Intl.

Question 1
Do you support the proposed scope, purpose and principles for natural health product legislation? If not, what other suggestions do you have?

Regarding the scope, to determine that a 'third category' distinct from foods and medicines may create disproportionate effects on nutrients and products for which there is a presumption of safety owing to very long historic use as foods or as dietary supplements. This disproportionate effect could be minimized if risk analysis of individual ingredients, extracts or other substances revealing very low risk (i.e. comparable or lesser risk than conventional foods) meant that such products were not subjected to onerous pre-market authorization or evaluation. We believe, for many products, the presumption of safety principle, which is based on historical use and known science (derived from knowledge of biochemical mechanisms, animal and/or human studies), is of key importance.

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Under the purpose of the legislation, it is stated: “It is proposed that the purpose of the legislation be ‘to provide assurance to consumers that natural health products are safe, true to claim and true to label’. This concept of safety is somewhat disingenuous, given that it is not for either a government or a manufacturer to ensure in absolute terms that products will always be safe. Less well known allergic and sensitivity reactions mean that labeling cannot always be used to provide warning to consumers; sometimes a very mild adverse reaction (e.g. loose stools from higher dosages of certain forms of magnesium) yield very positive health benefits. In reality there is not a discontinuity between risks and benefits as erroneously suggested by a number of international panels, including the Codex Committee on Foods and Special Dietary Uses.

This complication is described in detail in a recent peer reviewed paper (currently in press in the leading scientific journal Toxicology, the official journal of the British and German Toxicological Societies). The paper was produced by the Science Unit of ANH-Intl and is referenced below:

> Verkerk, R.H.J., Hickey, S., A critique of prevailing approaches to nutrient risk analysis pertaining to food supplements with specific reference to the European Union. *Toxicology* (2010), doi:10.1016/j.tox.2009.12.017.

The flawed risk analysis approaches adopted by some regulatory authorities, notably those in Europe, at least in relation to vitamins and minerals, have very rarely been subjected to proper validation. A second peer reviewed publication in the same journal (also still in press) reveals the fact that benefits and risks associated with micronutrients commonly overlap. The reference for the paper is as follows:

> Verkerk, R.H.J., The paradox of overlapping micronutrient risks and benefits obligates risk/benefit analysis. *Toxicology* (2010), doi:10.1016/j.tox.2010.02.011.

This suggests that it makes no sense to suggest that a product should be guaranteed by a government as safe, given that this typically leads to overly stringent restrictions which prevent consumers from benefiting sufficiently from natural health products. We would argue that the main requirement is that the consumer is given free choice over products that in relative terms are safe, but should there be specific risks for particular subpopulations are stated on labels as a risk management measure. This way, consumers are clearly informed of any known and potential risks, while the majority are able to benefit from the same products with no or negligible risk of any adverse health effect. This actually is the basis of food labeling in most countries, e.g. nut, dairy, gluten allergies/intolerances/sensitivities in conventional foods.

The common overlap of risks and benefits also means that it is inappropriate for risks to be considered in isolation. The above referenced paper demonstrates the importance of identifying a ‘zone of overlap’ in which risk/benefit analysis is undertaken.

The discussion document proposes two possible principles, namely:

- The level of regulatory control applied to natural health products should be commensurate with the risks associated with their use.
- Consumers should be supported to make informed choices about their use of natural health products.

With regard to the first, the former principle is of key importance (see above), meaning that uniform requirements should not be placed on all natural health products. It is quite possible to delineate particular risk groups, although it is generally easier to do this for individual substances than it is for products that may contain multiple substances, where the combined effects are not fully understood as a result of a lack of research.

Nonetheless, determining at least four risk categories would be a very useful starting point, namely:

a) Substances or products with **no known risk** of any significant adverse health effect

b) Substances or products with **low risk** of a specified and significant adverse health effect

c) Substances or products with a **moderate risk** of a specified and significant adverse health effect

d) Substances or products with a **high risk** of a specified and significant adverse health effect

Risk analyses required to create such categorisations should be undertaken on products in the forms, dosages and delivery systems in which they are intended to be used. Risk should relate primarily to long-term exposure of intended doses (short-term risks can be largely managed via product label warnings). In some cases, where risks are likely to occur from high level consumption over longer periods, label warnings which state that long term use (e.g. more than 6 weeks of continuous daily use e.g. for zinc supplements delivering more than 25 mg Zn) should be avoided as part of an effective risk management strategy.

The lack of consideration of differences in risk profile of different molecular forms of micronutrients, as currently is the case in the risk management work being undertaken by the European authorities in their attempt to harmonise minimum and maximum levels of vitamins and minerals EU-wide, creates disproportionate effects on the natural products industry. For example, should the risk for iron sulphate supplements be applied to iron bisglycinate when the latter form is not associated with the gastro-intestinal problems associated with the former at typical dosages used?

Problems associated with avoiding analyzing risks of different molecular forms of nutrients are considered in detail in the two ‘in press’ *Toxicology* papers referenced above.

Question 2
Do you think the scope proposed for the definition of natural health product is appropriate?

The discussion paper indicates: “It is proposed that the term cover products intended for oral use, or for application to the skin or hair, that contain generally low-risk ingredients that are derived from nature, or their synthetic equivalents.” It then goes on to say that extracts should be excluded.

The notion of excluding extracts is not rational given the long use of extraction

systems in natural health. It would be much more relevant to exclude extracts in cases when there was evidence of an unacceptable risk, e.g., because of excessive content of harmful alkaloids or glycosides.

Question 3
Are there products that would fall outside the definition that you think should be included? Conversely, are there products that fall within the definition that should be excluded?

What about animal products? These are sometimes of seminal importance to traditional medicinal cultures. Dried organ meats have also widely been used by CAM practitioners. To emphasise the nature of problems caused by omissions, the exclusion of minerals and animal products in the European Directive on traditional herbal medicinal products (Directive 2004/24/EC) has created major challenges for some of the longest standing traditional medicinal cultures, such as traditional Chinese medicine (TCM) and Ayurveda.

Any claim implying traditional use of a given ingredient or product should respect fully (and hence allow) the traditional use unless there are overt grounds to suggest excessive risk to particular subpopulations (that cannot be managed through labelling or other risk management practices) or there are known adverse environmental impacts that would result from usage of the substance (e.g. use of rhinoceros horn).

Question 4
Are there any other functions that you consider the advisory committee should have?

There could be serious problems with lack of transparency if the advisory committee is selected by the Minister for Health alone. While the discussion document considers broad representation, the selection process by a single Minister is unlikely to yield unbiased representation.

Involving stakeholders, academics, non-government organisations and relevant government departments in a democratic election process for the advisory committee that includes, amongst others, individuals who are deeply familiar with the specialists in the natural products industry, relevant areas of academia, the CAM community, traditional medicines, etc. would likely create a more objective and transparent committee that had been elected rather than simply being appointed. Appointment by a single Minister could easily create a bias of views and could attract negative views from the public and the industry. Representation needs to be very carefully considered and representation should be sourced not only from academic and industry bodies, but also from representatives from complementary and alternative medicine associations, medical doctors with a keen understanding and experience of natural medicine, consumer and environmental groups.

Risk categorisation could be a key function of the advisory group, so that different levels of quality control, purity, labelling and other relevant regulatory parameters could be applied according to the degree of relative risk.

Question 5
Do you agree with the concept of a consultative body and its possible role?

The concept of a stakeholders' consultative body is useful, but representation of such bodies in other parts of the world (e.g. Europe) tends to be biased towards relatively few of the largest stakeholders. These are often not representative of the large numbers of small to medium sized enterprises (SMEs) that make up a very significant sector of the natural products industry. Other interests, such as practitioners in the field of clinical nutrition, nutritional therapy and herbal medicine, are frequently completely omitted from such bodies, and this is problematic.

Question 6
Do you agree with the proposed self-certification scheme for product approval? If not, what would you like to see instead?

There is such sparse information given about the requirements for the proposed pre-market approval. Accordingly it is not possible to make any informed comment as to whether the procedure required would be problematic for most industry players, especially smaller ones which could otherwise be affected disproportionately.

In principle, and in the absence of detailed information on the technical requirements, pre-market approval only makes rational sense for products which, according to their intended usage, have the potential to give rise to a moderate or high risk of an adverse health effect to a particular (even a minority) subpopulation. The nature, severity and reversibility of the risk should be evaluated.

There is a substantial difference between pre-market authorisation and pre-market notification of products. It is important to recognise that European authorities have not established a pre-market approval system for all food supplements. There is only a positive list of allowed ingredients for vitamins and minerals which is harmonised across the European Union (EU), but other nutrients, such as botanicals and essential fatty acids, are not restricted to those on a positive list. Secondly, there is a pre-market notification requirement for food supplements in all 27 EU member states, except the UK, Netherlands and Sweden. Herbal medicines have a separate simplified medicinal licensing scheme under a separate directive (Directive 2004/24/EC). This system is a product licensing system requiring very onerous technical requirements and restrictive eligibility requirements. The system has failed to function effectively for non-European traditional medicines, as demonstrated by the fact that not a single TCM or Ayurvedic product has yet to be successfully registered under the centralised scheme

despite it being 6 years since the scheme was initiated. Therefore it is misleading to suggest that Europe has implemented a pre-market approval process for all natural health products.

We would suggest that if a risk categorisation procedure is implemented, pre-market approval is unnecessary and simply provides 'red tape' that reduces efficiency in both the natural health and the government regulatory sectors. Instead, pre-market notification, which could equally well be undertaken using the electronic online system proposed, would suffice in meeting the mandate proposed in the discussion document for the majority of products (negligible and low risk categories).

Question 7
Should an exemption from product approval apply to any particular types of natural health products (for example, certain homoeopathic preparations or aromatherapy products)? If so, please specify which types of products and indicate why you consider an exemption should apply.

Negligible risk or low risk products should be exempted as they share risk profiles that are equivalent or even more favourable (less risky) than conventional foods. Therefore the regulation would act disproportionately if more stringent requirements were given. A pre-market notification, rather than approval, system, would still ensure that the regulatory authorities had full knowledge over those natural health products present on the NZ market.

Question 8
Are there other situations in which it should be permissible to supply natural health products without a product approval?

Via medical doctors and licensed practitioners.

Question 9
Are there specific lists of substances used in other jurisdictions that you think should become part of New Zealand's list of permitted ingredients? If so, please specify.

Pre-market approval should be restricted to products that have a moderate or high risk of exerting some type of adverse health effect (see above) on a given target population. It is clearly useful to allow mutual recognition of evaluations carried out in other jurisdictions, such as the EU, USA, Canada and Australia. Where a product is substantially equivalent it should be able to be 'fast-tracked' via a simplified approval system.

Question 10
Do you think there should be a list of prohibited ingredients, as well as a list of permitted ingredients?

All substances have the potential to be harmful so the severe risk to human health that would be the key factor determining inclusions on any prohibited list should be based on a given dosage of a particular substance. Prohibiting substances *per se* without specifying any inclusion level or dosage is not rational scientifically. A positive list is also useful, however, we strongly disagree with a Napoleonic system as used in Europe (e.g. for vitamin and mineral forms) where all ingredients other than those on the positive list are banned.

Question 11
Are there specific claims used in other jurisdictions that you think should become part of New Zealand's list of allowable claims for natural health products? If so, please specify.

The approach to the determination of health claims as being pioneered at a regulatory level by the EU, and to a lesser extent by the Food and Drug Administration (FDA) and Health Canada (which is broadly in line with the health claims guidelines developed by the Codex Committee on Food for Special Dietary Uses) is almost unworkable. The key problem relates to the requirement to have "generally accepted scientific evidence" to support causal relationships ('cause and effect') between a food or food ingredient and a beneficial effect on human health.

In its evaluation of submitted health claims in the EU, as of the time of writing, EFSA have evaluated 939 generic health claims submitted by the interests in the EU food industry. Of these only 82 have been positive. The key reasons for rejections have been one or more of the following:

a) inadequate characterisation

b) lack of evidence that the claim is physiologically beneficial to health

c) inadequate evidence base

d) wrong target group (e.g. osteoarthritis sufferers as opposed to healthy individuals)

It makes no sense to only allow claims on the basis of conclusive evidence on healthy populations only. Is a healthy population one that is not exhibiting any risk factors or symptoms of disease? Should all research evaluating the effects of botanicals, nicronutrients, essential fatty acids, amino acids and other micronutrients really be ignored? Does it really not serve us — or the consumer — with any useful information? We believe that the consumer needs to elements in particular:

1. The consumer must not be misled, and

2. The consumer must be given credible evidence that is qualified or even

graded according to its conclusivity. The evidence must have biological plausibility. Above all, however, it does not and should be required to be conclusive.

Such a scientific and regulatory culture, as presently being practiced in Europe, will mean a very large number of health relationships will not be able to be communicated, thus leaving consumers with less rather than more information. This ultimately will lead to a disservice to consumers and it would likely stimulate growth of a black market of unregulated products with unregulated claims. This is presently the direction the EU is going in (full implementation has yet to occur and will not occur until EFSA has completed evaluation of over 4,600 generic health claims which is not expected until December 2011). Additionally, widespread opposition from industry and consumer groups within the EU means that change to the European health claims regime may occur in due course.

To summarise, the most important requirements for health claims is to ensure that they are credible and scientifically plausible, rather than conclusive by way of generally accepted scientific evidence supporting a causal relationship between a health benefit and a specific food or food ingredient.

A recent court judgment in the US has overturned the FDA's decision to withdraw the selenium/cancer risk reduction qualified claim that was previously granted. More information on the case is given on the ANH Europe website, viz: http://anh-europe.org/news/anh-press-release-court-victory-against-fda-for-free-speech (published 31st May 2010). Most importantly, the court ruled that on the basis that there was credible evidence for a health claim made, that claim should be made and any attempt by the regulator to deny this would constitute a restriction on free speech.

Question 12
Do you believe that the regulator should conduct audits to assess compliance with the requirement that sponsors hold evidence to support natural health product claims?

It is reasonable for a regulator to periodically check that claims being made by the industry are credible and can be substantiated with scientific evidence. However, it is inappropriate for these claims to be based only on human studies (much of the risk evaluation of pharmaceuticals is after all based largely on animal studies). All claims can be qualified in one way or another and such qualification allows credible evidence to be passed to consumers and it gives consumers a clearer picture of the qualification of the evidence. This interpretation of qualified health claims is more appropriate for:

- Emerging science
- Food constituents that have not been well studied as they are presumed to be of significant health benefit given a thorough knowledge of their constituent components (e.g., phytochemicals)

- Food constituents, the effects of which have not been studied on healthy populations (most studies have focused on diseased populations for which a particular therapeutic outcome was being investigated. Historically, it has been hard for companies to justify studies of healthy populations.

Question 13

Do you agree with the proposed list of labelling requirements? If not, are there requirements that should/should not be included?

We agree with those points proposed, but also propose additional points:

- Allergens should be clearly stated
- Where botanical ingredients are given both common and scientific names should be given
- Products containing Genetically Modified (GM) ingredients
- Animal-based products derived from GM feed
- Advisory warning statements to protect any subpopulations that might be susceptible to any adverse health effects.

Question 14
Do you agree that an exemption from the general labelling requirements should apply to products that are 'tailor-made' by a natural health practitioner for supply to an individual? If so, what do you think the labelling requirements for such products should be?

The minimum labelling requirement should still be:

a) formulator and contact details

b) full list of ingredients in descending order of weight. Where botanical sources are given, scientific names should be included.

c) net contents

d) any relevant warning statements (incl to keep out of reach of children)

Question 15
Are there other situations where a labelling exemption should apply?

No.

Question 16
Do you agree with the proposed minimum requirements for advertisements? Is there any other information that should be included?

The requirements proposed generally appear sensible and intended to ensure the consumer is not misled.

Question 17
What information should be required to be provided in radio and television advertisements?

Any advertiser should have on file the evidence on which to substantiate any claims made prior to the publishing of the advertisement. The manufacturer and brand name(s) should be clearly stated.

Question 18
Are there any other types of advertising for which different requirements should be set?

No comment.

Question 19
What impact do you envisage the proposed regulatory scheme will have on the ability or willingness of businesses to export natural health products?

The New Zealand industry is substantially different to the Australian industry and contains, relatively, a much higher proportion of raw ingredient suppliers. The burden of proof of safety of raw ingredients should be accepted by manufacturers and any attempt to cloak the raw ingredients industry in a complex approval system would likely negatively impact the New Zealand industry and give a competitive advantage to less regulated markets for raw ingredients such as India and China.

Question 20
How would having to obtain product approvals for different markets affect your willingness or ability to export?

No comment — given that we are neither an importer or exporter, but rather a not-for-profit organisation supporting the natural products sector.

Question 21
Do you agree that a code of practice for the manufacture of natural health products should be developed? If not, what standards do you think should apply?

It would seem reasonable to develop a code loosely built around HACCP.

No further comments are made on the consultation paper.

Should there be any questions, please don't hesitate to contact us at:

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