

**PROPOSED MODEL FOR THE
REGULATION OF DIETARY
SUPPLEMENTS IN NEW ZEALAND**

SYNOPSIS

CREATED AND PRESENTED BY
THE NEW ZEALAND HEALTH TRUST
SEPTEMBER 2003

INTRODUCTION

The New Zealand Health Trust is a Charitable Trust which contains amongst its objects the monitoring of health issues in New Zealand and the promotion of public awareness of their own health and the options available to them.

The New Zealand Health Trust has been heavily involved in the current proposals to review the way in which Dietary Supplements are regulated in New Zealand and strongly opposes the stated Ministry of Health proposal to join with Australia in the establishment of a Joint Trans-Tasman agency which will be responsible for the regulation of all therapeutic products including pharmaceutical medicines, medical devices and dietary supplements (the “JTA”).

The arguments advanced by the Trust in opposition to the JTA proposal are set out in full in the following documents which have been filed with the appropriate parliamentary agencies and which are available from the Trust by request:

- August 2002 -Original submission to the Ministry of Health in response to their discussion document
- November 2002 – Signatory to the collective submission of the Dietary Supplements Consultative Group to the Health Select Committee Enquiry into the proposal to establish a JTA.
- June 2003 –Constitutional, economic and business impact evidence to the hearings of the Health Select Committee
- August 2003 – Further submission to the Health Select Committee in relation to the presentation of Medsafe and the Australian Therapeutic Goods Administration (“TGA”).

For further information on the JTA proposal or the basis for the Trusts opposition to it please contact the Trust. For present purposes it is sufficient to record that the JTA model is seen as being problematic in the following regards:

- It is predicted by economists to have a severe impact on the compliance cost burden on New Zealand dietary supplement businesses
- It is estimated that a significant number of NZ businesses would go out of business as a result whilst at the same time providing an economic benefit to the counterpart businesses in Australia
- High level constitution advice indicates that there are considerable difficulties in delegating all power to regulate a New Zealand Industry to a body to be established by the Australian government, which will be located in Australia but which will be technically responsible to both governments.
- Forcing dietary supplements to be regulated within the pharmaceutical regime is unwarranted and impractical and there is no evidence that any better consumer protection is achieved as a result.
- The proposal pays no heed to, and is out of alignment with, the actual risk profile of dietary supplements which is extremely low.
- The system has been demonstrated in Australia to in fact increase non-compliance because the cost to comply is so onerous.
- The proposal does not meet the New Zealand Government’s own Code of Good Regulatory Practise

- Harmonisation with Australia will limit our ability to trade easily with our major trading partners in a way that Mutual Recognition would not.

As a result of the Trust's involvement with this process of considering the available options for the regulation of Dietary Supplements, the Trust reached the view that a regulatory model could be created that met the stated concerns of the regulators (the Ministry of Health) whilst avoiding the problems inherent with the JTA model proposed. For this purpose we summarise the stated concerns of the Ministry of Health as follows:

- Knowledge of what is on the market
- The accessibility of that information to both regulators and consumers
- Safety of products to end consumer
- Justification of claims made.

In order to demonstrate the ability to meet the above concerns without placing an unfair burden on Industry, the Trust resolved to develop an alternative model for presentation to both the Health Select Committee and the Ministry of Health to demonstrate that there is no need to pursue the highly problematic JTA approach.

The Trust has now completed the framework for this alternative model and is currently finalising the technical aspects, financial projections and codes of practise documentation for the model.

The model has to date been produced at the sole expense of the Trust and its sponsor David Sloan to demonstrate a better regulatory approach that meets public safety and consumer protection issues without placing an unnecessary and unjustified burden on the dietary supplements industry. The model is designed to support the viability of the industry, encourage innovation and increase consumer knowledge and understanding so the public can take an increased responsibility for their own health and well being.

This document is intended to give an overview of the operation of the proposed model without providing all the specific detail of the same. For more information on the proposed model or to receive a full presentation of the same from the Trust please contact the Trust using the contact details below.

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SCOPE OF REGULATION

In general terms the model will operate to license all manufacturers, importers and suppliers of dietary supplements in New Zealand and have all dietary supplements available for sale in New Zealand produced in accordance with good manufacturing standards applicable to each stage of the production process. All products will additionally be compulsorily listed by the supplier of the product (including an importer) on a publicly available internet based database which shall provide complete, accurate and up to date information regarding that product to both the consumers and regulators alike, although the more confidential information will only be available to the regulators for reasons of commercial sensitivity. The listing system is one of notification by the producers. It does not involve pre-market approval or vetting which is one of the leading objections to the JTA system and the primary reason for the significant cost burden of that system.

The regulators would likely be the Ministry of Health and it is strongly advised that a separate branch of the Ministry be established for this purpose, staffed with people qualified and experienced in the natural health field as distinct from those with pharmaceutical backgrounds and pre-conceptions.

By way of explanatory comment, it should be noted that traditionally, and until now, dietary supplements have been classed in New Zealand as a sub-set of foods in keeping with their natural, food based origins and their low risk profile.

As stated in the introduction section above, the proposals currently promoted by the Ministry seek to move dietary supplements from this broad categorisation and include them instead with pharmaceutical, synthetic medicines. The dietary supplements industry has long advocated that dietary supplements rightly belong in a category of their own distinct from both foods and medicines. For every example of a supplement where it is arguably hard to distinguish the line between supplement and medicine there are many more where it may be hard to draw the line between supplement and food. Neither the food or medicine category is therefore an appropriate fit for these products.

There is the additional difficulty of the methods by which efficacy of products is established. For pharmaceutical products expensive clinical trials are the norm and are justified by the ability of the producer of the synthetic product to patent the same and re-coup the vast investment that such trial require. Additionally the high risk nature of pharmaceuticals requires that they be subjected to the most rigorous of testing before being made available to the public.

For dietary supplements however, as part of the natural health field, efficacy is based on results based data and is warranted by the predominantly natural composition of the products, the long history of their usage and most importantly the very low risk profile they enjoy. In the same way that it would be nonsense to require a producer who wanted to offer a liquid form of bananas to undertake clinical trials, it is equally nonsense to impose such requirements on the producers of dietary supplements which are mostly just the refined versions of natural and food derived products.

That is not to say of course that there should be no limit on the efficacy claims that can be made in relation to products for that is a separate matter and is addressed later in this synopsis. The issues of trials and testing is one of product safety and on that ground there is

nothing in the historical use of dietary supplements which justifies treating them any differently to that way we treat foods that are produced for sale which requires of course that basic hygiene and storage requirements must be met.

Based on the above therefore, dietary supplements must be assessed on their own merits and regulated in line with their own risks. They do not fit within any pharmaceutical framework and it is this basic conceptual error which is at the heart of the flaws in the proposed JTA. This model suggests the development of a separate Natural Health Products category under the overall jurisdiction of the Ministry of Health whilst remaining in all ways separate from the business units of the Ministry which are charged with regulating pharmaceutical medicines.

The regulatory framework will be created under a specific Dietary Supplements Act of Parliament and Regulations enacted under the same.

It is suggested that in addition to the specific Ministry of Health division, an Industry Advisory Panel be formed to assist in the assessment of all issues and represent the industry position for the same.

Prohibited products or dosages will continue to be controlled by way of a clearly stated and easily accessible 'negative list' which is able to be updated as needed by the regulators.

The regulators will also co-ordinate an impact reporting system which encourages the reporting of experiences with dietary supplements, either positive or negative. This system will provide the basis for the referral of some products to testing where concerns have arisen due to a pattern of reports, and in time may itself provide a level of evidence to support the making of product claims. Both of these matters are discussed further below.

FEES & LICENSING SYSTEM

The model requires all New Zealand manufacturers and suppliers (including importers) of dietary supplements to be licensed by the regulator. Each business will have to do a number of things in order to obtain a license and the requirements will vary between the different license types as noted above. The applying business will have to show that it has an appropriate and approved code of practice in place for its business. This requirement is detailed further below. The applicant, and if a company, the shareholders, will have to certify that they have not been banned from holding such a license and the appropriate fees will have to be paid.

The projected fees are currently being developed with the assistance of an economist who is creating budgetary models for the proposed regulatory system. The fees will include an application fee for new licenses and an annual renewal fee. In addition to the licensing fees, the system provides for various cost recoveries from non-complying businesses as further detailed in the enforcement section below.

This model is capable of being fully self-funding if required. There is however a strong argument that complementary tax payer funding is warranted for dietary supplements given that they have a large public good component such as adding considerably to keeping the public at large healthy. This then reduces the demand for, and therefore cost of, public health

services. Further, unlike the European Union, dietary supplements in New Zealand are not government subsidised in the same way as pharmaceutical medicines.

Whilst the option exists to charge for each product listing on the internet based directory detailed below, it is intended that no charge will be levied on these changes if at all possible as the philosophy of the regulatory model is to make full and honest compliance easy for the businesses. Should they incur a cost each time they modify the directory information then the temptation will exist not to make all the necessary modifications. The more accurate and up to date the directory information is, the better the system will work. Therefore the fees are instead all collected by way of the annual license fees.

Each business only pays one fee per year. From these fees the regulators contract out the operation of the internet based database and pay the on-going administration of the regulatory agency and the random audits and product testing of some dietary supplements as an aid to ensure compliance and to investigate any products of concern. The size of the fee will vary between businesses, determined by a number of factors including the size of the business and the number of products it produces. Equally the fees will vary between suppliers and manufacturers accordingly to the burden each places on the regulatory system.

The terms of the License will impose a number of obligations on the businesses including:

- The requirement to only deal with other businesses who hold the appropriate licenses.
- The requirement to enter all business and product details on the web based directory and to update and amend these as required.
- If claims are made for a product that these are made in accordance with the regulatory claims guidelines produced as part of the regulatory system proposed and detailed further below.
- The requirement to only make products that comply with the dietary supplements regulations.

GOOD MANUFACTURING PRACTISE STANDARDS

It is recognised that as for all products created for human use or consumption, systems must be in place that ensure the final products are of a consistently high quality.

Most businesses involved in the dietary supplements industry have already identified for themselves the potential hazards and critical control points for their business and have developed strategies to deal with these hazards. Many industry groupings have codified these standards into codes of practises that bind all their member businesses.

The proposed model recognises the importance of such systems and makes having an appropriate and approved GMP code mandatory for all manufacturers and suppliers of dietary supplements.

In the same way that the regulators of foods in NZ have recognised that each business is in the best position to assess and plan for the specific risks in that business, the proposed model provides for each business, either individually or collectively through industry groupings, to

set their own appropriate GMP code covering the prescribed minimum requirements. Once a business or industry grouping has developed their code, that code must be approved by the regulators as meeting the required standards. This check is done at the initial license application stage. As stated above, for many existing businesses these standards are already in place and this will just codify these standards and will not impose any further obligations on each business. It will however ensure that all licensed businesses meet the same high standards and work to avoid any industry “cowboys”.

CLAIMS GUIDE

A dietary supplements claims guide is being written as part of the proposed regulatory model.

The manual is designed to enable all businesses in the industry to know with a degree of certainty what claims can and cannot be made in respect of dietary supplements and what information or knowledge is required to justify the making of them.

If the supplier of a product wants to make a claim then it is proposed that the acceptability of that claim will be assessed from the following perspectives;

- (1) Firstly the severity of the condition involved is relevant to both the making of claims and the evidence required to justify those claims. The more serious the condition involved, the greater the level of evidence that will be needed.
- (2) Secondly, the strength of the claim made is of relevance. For example a claim to “cure” or “prevent”, if allowed at all, will require a greater evidential basis than a claim to “assist in the prevention of ...” or a claim that the product “may help in relieving the symptoms of”.
- (3) Thirdly the appearance of warnings alongside the claims may alter the level of supporting evidence that would otherwise be required. For example it may be that a clear statement that the dietary supplement will only be effective if dietary intake is inadequate would modify the level of evidence required. In the United States for example products claims are often qualified as follows “this statement has not been evaluated by the Food and Drug Administration”. Making it clear that the claim represents the supplier’s own opinion or is not intended to diagnose, treat, prevent or cure any disease may similarly limit the evidence required to be held.
- (4) For claims made the supplier would warrant that they hold the appropriate evidence which could be made available to the regulators on request or during audits.
- (5) Claims would continue to need to be accurate and not misleading.

The Claims Guide is designed to reach an acceptable balance between the principles of consumer sovereignty and the requirement to protect the more vulnerable sections of society. It is recognised that suppliers and retailers are already bound by general consumer protection legislation and are accordingly under a requirement not to mislead or deceive in relation to any products they sell. Whilst they must therefore act honestly, it is important that

consumers are encouraged to educate themselves as to all available options and, bearing in mind the low risk profile of dietary supplements, find out what produces good results for them. Clearly a product may work in different ways for different people and therefore the ultimate decisions as to efficacy must be the consumers, unhampered by decisions of regulators as much as possible.

INTERNET BASED PRODUCT DIRECTORY

At the heart of the proposed model is the internet based products directory.

As already noted above all licensed businesses are required to list the details of all products they supply on this directory (except for exempted products such as one off products created for a patient by a practitioner). It is anticipated that these details will include label information and such other basic information as the regulators determine. The emphasis is on keeping this a simple and easy to comply with system.

The purpose of the directory is two fold. Firstly it provides the regulators with important, accurate and up to date information about all products available in New Zealand. Should a product recall be required the information as to what is available that may need to be recalled and the possible locations of those products will be easily able to be accessed. In addition it enables the regulators to closely monitor all products as to ingredients and claims from one centralised location thereby making enforcement easier.

The second purpose of the directory is to ensure consumers have access to high quality, consistent and current information about any product. Any one will be able to use the site to carry out a variety of free searches including searching by product name, health condition, ingredient and so forth. Once a search is completed and a product of interest identified, the user is taken to the full product information page including information on how the product should be used. This function of the directory provides a valuable public safety function by ensuring the correct information is always readily available to consumers who may otherwise be taking it based on informal suggestions from friends or may have lost the original packaging containing that information. In addition more information will be able to be provided to consumers than can realistically be included on a product label.

The availability of the directory for consumer searching provides another important function. It is anticipated that the directory will quickly become the primary source of consumer reference for sales of dietary supplements as a free and objective service. This being the case it becomes in the interests of each business involved in the dietary supplements industry to ensure that all their products are listed on the site, quite apart from the legal requirement to do so. Once again encouraging compliance and thus reducing the enforcement levels and costs required.

The web base directory has been named myHealth and is nearing technical completion. A demonstration of the software and site capabilities is available on request.

ENFORCEMENT

The budgets for the system from which the licensing fees are to be set includes the costs of carrying out random paper based audits to confirm proper compliance with the applicable GMP standards. In addition there is a budget for a yearly quota of product testing which can be used in response to product complaints, tip-offs or in the absence of these, for entirely random testing.

Where the audit and/or testing reveals no breaches then the cost of the same is fully met by the regulatory budget. In the event however that any areas of non-compliance are found then the cost of such reasonable audits and/or testing as may be required will be charged to the business concerned as will the cost of reasonable follow up testing after a period of six months to ensure any deficiencies have been rectified.

A series of offences and penalties will be created as part of the legislation that are to be staggered so as to be appropriate to the severity of the offence. As well as monetary fines, the most serious of offences will carry a penalty of loss of license that may be temporary or permanent. Procedures will be in place for product recalls where there are clear grounds for the regulators to suspect a serious risk to the public if a recall was not made.

Once again the penalties are designed to create a fair balance between being a proper deterrent to non-compliance and not to impose a heavy burden on businesses for minor errors of little practical impact.

CONCLUSION

The model is centred on the proper information being available to the consumers and regulators at all times along with a system being in place to ensure consistency in product quality.

Once operational, the model will be able to be presented to other international regulatory bodies as the basis for mutual recognition treaties with such countries to enable reduced trade barriers between New Zealand and those other countries. Mutual recognition is now seen by many as the optimum model for the encouraging of international trade. It enables co-operation to be reached with many trading partners and has been established by independent reviews to be likely to result in increased economic growth for the countries concerned.

Whilst Australia is in favour of a harmonisation approach, this is because that will be of benefit to Australia. Harmonisation will tie us to them in such a way that the effective trade barrier they have will equally apply to New Zealand and limit our ability to trade freely with other major trading partners. Under mutual recognition however trade opportunities are maximised and Australia would, under the WTO rules, be prevented from denying New Zealand products access to their markets once New Zealand can show it has a rigorously regulated system resulting in the production of safe products.

By adopting the model proposed the following major benefits accrue:

- consumer protection is enhanced
- the industry remains controlled from within New Zealand,
- no constitutional difficulties arise,
- compliance costs are kept to a minimum, supporting business viability and

- international trade opportunities can be maximised

The New Zealand Health Trust has developed the proposed model in consultation with industry representatives and is confident that full industry support would be given to this model in preference to the JTA proposal.

The component parts of the model involved significantly more detail than is able to be presented in this synopsis. This document is intended to give an overview only of the proposed regulatory model and should not be taken as a full statement of the same.

The New Zealand Health Trust would welcome the opportunity to present the model to you in more detail upon request. Whether this model is accepted in its present structure or as modified, this synopsis is designed to illustrate the potential that exists to develop and apply a model for the regulation of dietary supplements that does not have the significant difficulties associated with the JTA approach.

We recommend that the JTA approach be rejected and the Ministry of Health undertakes a period of proper industry consultation to refine the detail of this model.

September 2003.