

4 March 2016

To: Natural Health Products, Ministry of Health

Subject: **SUBMISSION FROM THE NEW ZEALAND HEALTH TRUST ON THE REGULATION OF NATURAL HEALTH PRODUCTS**

## **EXECUTIVE SUMMARY**

### **Introduction**

The Natural Health and Supplementary Products Bill and its associated regulations would bring a wide range of natural health products currently used safely every day by New Zealand families and consumers into a new system of government regulation.

Natural health products are low-risk products. No Coroner in New Zealand has attributed a cause of death to a natural health product.

The Natural Health and Supplementary Products Bill is draconian and heavy-handed “Nanny State” regulation. It is not evidence-based, and represents dramatic bureaucratic over-reach to deal with a non-existent public health problem.

### **Flawed consultation process**

The Ministry’s current consultation on the regulations it intends to promote with the Bill is fundamentally flawed. The consultation documents seek feedback on a Supplementary Order Paper to the Bill that is not currently publicly available.

The Ministry has told the sector that it plans to make further changes to the Supplementary Order Paper before its introduction to the House. These proposed changes are not yet publicly available.

### **Bureaucratic over-reach and compliance costs**

The Bill imposes substantial and unjustified compliance costs. For example, the Bill requires all products to be notified at an annual fee of just under \$200. A notified with 1000 products would be required to pay almost \$200,000 in annual notification fees.

The Bill requires all ingredients in natural health products to be pre-approved through a bureaucratic process by a new government regulator, at a cost of around \$2-3 million per year according to the Ministry’s estimates.

Trying to create a comprehensive list of all safe potential ingredients in the natural world – in this case including products that are already sold as foods and even including different “categories” of water - is an absurd use of public resources and represents extraordinary bureaucratic over-reach.

For example, the cost of preparing evidence that satisfies the proposed regulatory system for approval of a single permitted ingredient could be anywhere between \$40,000 and \$150,000, according to the experience in Australia.

To put that in context, during the limited consultation period to date, at least 2000 ingredients that were omitted from the Ministry of Health's draft list of around 5500 permitted ingredients have been identified.

The Bill and regulations also impose new compliance costs around manufacturing.

### **Barriers to competition**

The costs of the new regulatory agency would fall on the sector through various fees, including product notification fees and fees for approving new ingredients. The proposed scheme's prohibitive costs would fall mainly on small and medium manufacturers, who tend to have lower turnover on a wider range of products.

It therefore creates barriers to competition protecting larger manufacturers, who tend to support the Bill.

These features would inevitably cause a reduction in the number of natural health products available to be sold by New Zealand firms in the New Zealand market. Consumers would be forced to buy products on-line because the products simply won't be available in New Zealand.

### **Unnecessary duplication of responsibilities**

The Bill and regulations also regulate the types of health benefit claims that can be made for (non-therapeutic) "allowable claims" for "named conditions".

There are currently sufficient protections against making unsubstantiated claims in the recently amended Fair Trading Act 1986. Substantial fines are imposed on individuals (\$200,000 maximum fine) and companies (\$600,000 maximum fine) that breach the Act. There is no evidence that the Commerce Commission is failing its enforcement responsibilities in this area.

There are no legitimate safety concerns that justify the Bill.

### **Unintended consequences for exports**

The Ministry believes that the Bill would contribute to an increase in exports from \$1 billion to \$5 billion by 2025.

This is wildly misconceived. The value of natural health product exports is significantly less than \$1 billion and is estimated to be less than \$200 million. The Bill's onerous requirements, including the requirement that export only products must only contain permitted substances, would stifle exports rather than encourage them.

### **Conclusion**

The New Zealand Health Trust believes this legislation and accompanying regulations should not proceed.

## INTRODUCTION

1. The New Zealand Health Trust is an independent, charitable trust. Its objective is to educate New Zealanders to make informed decisions about their health and wellbeing.
2. This submission is NZHT's response to the Ministry's consultation document entitled The Regulation of Natural Health Products.
3. NZHT has deliberately chosen not to answer the specific questions posed in the consultation document as it opposes the Natural Health Products Bill as being flawed in principle. Responding to the questions in the format presented in the consultation document would wrongly signal that NZHT agrees with the proposed scheme.
4. NZHT strongly opposes the Natural Health Products Bill.
5. The natural health product sector is important to the economy as it supports a number of jobs, research, manufacturing, and exports. It is critical that natural health products are regulated in a manner that reflects their overall low risk. No Coroner in New Zealand has ever attributed a cause of death to a natural health product. Extensive risk analyses demonstrate that natural health products pose a de minimis risk.
6. The Bill fails to take a risk proportionate approach and seeks to regulate natural health products in a manner akin to pharmaceutical drugs. This is unjustified over-regulation that would significantly damage the industry and limit consumer choice.
7. The form and structure of NZHT's submission is in three parts.
  - a. Part 1 identifies a significant flaw in the consultation process. The Ministry is consulting on the basis of SOPs that substantially amend the publicly available version of the Bill. The SOPs have not been published or made available as part of the consultation process. Meaningful consultation requires these documents to be publicly accessible.
  - b. Part 2 addresses the consultation topics and explains how the proposals are inconsistent with the principle that regulation of natural health products should be proportionate to the known risks associated with their use.
  - c. Part 3 explains that officials and the Health Select Committee have been justifying and promoting the Bill on the fanciful basis that it would contribute to an increase in exports from \$1 billion (currently) to \$4 billion or \$5 billion by 2025. These figures, both as to current and projected export values, are wildly inflated and bear no resemblance to reality.

## PART 1: CRITICAL FLAW IN THE CONSULTATION PROCESS

8. The consultation document says that a copy of the Bill being consulted on can be found on the Government's legislation website. However, the Bill is proposed to be substantially modified by a draft Supplementary Order Paper dated 18 August 2015 (SOP).
9. NZHT has also been advised by the Ministry that some changes introduced in the draft SOP have been further amended or removed and that a final SOP is expected to be published by the first week of March (which is after the consultation period closes).<sup>1</sup>
10. Neither the draft SOP nor any revised SOP is available online.
11. It is clear from the discussion about the permitted substances list that the Ministry is consulting on the basis of the unpublished SOPs. The expression "permitted substance" was only introduced through the SOP dated 18 August 2015.
12. This is significant because the SOP dated 18 August 2015:
  - Substantially amends the definition of a natural health product and now excludes all substances listed in the Schedule to the Medicines Regulations. This amendment is directly contrary to the clear intentions of the Select Committee that only medicines consented to by the Minister are excluded from the definition. The Committee was particularly concerned that honey could continue to be used as an ingredient in a natural health product even if it was a consented medicine.<sup>2</sup>
  - The amendment proposed would enable the pharmaceutical drug regulator to regulate honey as a medicine, and consequently prohibiting the use of honey as a natural health product ingredient.
  - Now requires export-only products to be notified. This means that export-only products can only contain permitted substances. It also prevents products being manufactured in New Zealand that are legal in trading partner countries.
  - Now requires all manufacturers of natural health products other than a health practitioner to be licensed.

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<sup>1</sup> Email from MOH dated 23 February 2016

<sup>2</sup> Committee's comments at p 4 of the Commentary: *We were concerned that a product such as honey could be registered as a medicine, which would then remove it from coverage under the bill. If a particular honey product were approved for distribution as a medicine, it could not also be notified as a natural health or supplementary product. However, honey could continue to be used as an ingredient in natural health or supplementary products. A product approved for distribution as a medicine is not included in the definition of a natural health or supplementary product in the bill as amended.*

- Prevents health practitioners from prescribing non-permitted substances to individual clients. Although the Ministry has now advised that the further amendments to the SOP would permit practitioners to use non-permitted substances.<sup>3</sup>
  - Amends and reduces the threshold concentration for a substance not to require product notification from 20 parts per million to 10 parts per million to align with high risk Medicines Regulations. However, the Ministry has now advised that the SOP has been further amended to revert to the 20 parts per million threshold.<sup>4</sup>
13. Meaningful consultation requires the public to be able to have access to the relevant SOPs. Failing to make these documents available for public inspection means the Ministry has not discharged its consultation obligations. The process is fundamentally flawed.

## **PART 2: CONSULTATION TOPICS**

### **Permitted substances list**

14. The lynchpin of the proposed regime is the permitted substances list. The premise underpinning the list is that unless an ingredient is permitted it is prohibited, or banned.

### ***Reasons why the permitted substances list is opposed***

15. There are three objections to this aspect of the scheme.

#### *Permitted substances list is not risk-proportionate*

16. The position that a substance is banned unless it is expressly allowed, is anathema to the principle articulated in the Bill that regulation should be proportionate to the risks associated with their use.
17. To require thousands of common foods and food additives to be specifically approved by a new regulator is absurd, defies logic, is incompatible with the Government's Code of Good Regulatory Practice, and is the antithesis of risk proportionate "light-touch" regulation promised by the government.
18. While novel (new to nature) ingredients with no history of safe use, such as pharmaceutical drugs, can be assumed hazardous unless evidence suggests otherwise, ingredients with a significant history of safe use such as those included in natural health products, should be assumed to be safe unless there is contrary evidence. This policy has served countries such as the United Kingdom, the USA and New Zealand

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<sup>3</sup> Email from MOH dated 23 February 2016

<sup>4</sup> Email from MOH dated 23 February 2016

well for many decades with very few safety issues arising. In New Zealand, no Coroner has ever attributed a cause of death to an industrially produced natural health product.

19. In other words, industrially produced natural health products pose a de minimis level of risk to consumers.
20. A permitted substances list that requires every single ingredient, including each type of water (such as purified, spring-water, seawater, glacial water), milk (from each species of animal such as cow, buffalo, sheep, goat etc), common fruits such as blueberries, each variety of honey, simple additives, flavourings and a large number of substances that are currently in use on a daily basis and have a history of safe use to be pre-approved by a new regulator, is not risk proportionate.
21. The Ministry of Health is applying pharmaceutical drug style risk management to natural health products and requiring proof of safety before permitting ingredients to which New Zealanders have had unfettered access with no safety concerns. For example, it is proposing to prohibit 5-hydroxytryptophan based on the fact that Australia has had an unsubstantiated case report some 20 years ago raising concerns. Canada and the USA do not prohibit 5-hydroxytryptophan and neither has New Zealand until now.<sup>5</sup>
22. This is not a risk proportionate approach.
23. NZHT believes that a reason the pharmaceutical drug approach is prevailing is because Medsafe is driving the Bill.
24. It is clear from documents obtained under the OIA that the work on the Bill is being done through Medsafe and that Medsafe is proposed to be the authority.
25. Medsafe's involvement in the Bill is explicitly contrary to assurances Government and officials gave to the Health Select Committee in 2012 that Medsafe would not be directly involved.
26. Medsafe regulates novel pharmaceutical drugs and is an inappropriate body to regulate natural health products. It is inappropriate because a different mind-set is required for natural health products. It is also inappropriate because of longstanding competing interests between the two sectors.

*The list would inevitably exclude safe ingredients*

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<sup>5</sup> See Canadian monograph at <http://webprod.hc-sc.gc.ca/nhpid-bdipn/>

27. Because the present draft list of permitted substances contains only a fraction of the substances available in nature (there are literally millions of ingredients both known and unknown), it is inevitable that once the Bill is passed, a large number of products would become unlawful even though they pose no credible safety risk.
28. Already many hundreds of hitherto safe ingredients have been omitted either through deliberate action, or oversight due to lack of regulator knowledge and understanding of the industry. NZHT is aware that Natural Products New Zealand (NPNZ) has stated publicly as recently as in the last month, that a further 2000 ingredients should be added.<sup>6</sup> That such a high number of ingredients have been omitted demonstrates the flawed nature of the permitted substances list.
29. A risk proportionate system would not have this consequence which is an unreasonable and unfair outcome for consumers and industry.

*Cost of obtaining approval for a new substance likely to be prohibitive*

30. The cost of getting a substance approved is likely to be prohibitive. The cost is likely to be comparable to the cost of getting a substance listed in Australia (because the criteria appear similar). This cost could apply to an everyday food item that has a long history of safe use.
31. NZHT has spoken to consultants experienced in this area and has learned that in Australia (which operate a similar approval system) the cost to prepare an application for a new substance is approximately \$40,000. These are principally the various consultants' costs to obtain and prepare the necessary supporting information, including literature searches and toxicological reports. If no toxicological data is available, it could cost up to a further \$150,000 to obtain the necessary information to prepare a toxicological report.
32. NZHT understands that the cost of getting bovine colostrum approved in Australia was over \$100,000 with officials insisting on safety studies before approval. However, it would cost nothing if bovine colostrum were sold as a food as it currently is. This is absurd.
33. There is an additional significant deterrent to bringing an application for a new permitted substance. Once a substance is on the permitted substances list, any other person can use the ingredient, and no advantage is conferred on the person who spent the money to have the substance approved. Unlike novel pharmaceutical drugs, natural substances have no patent protection. NZHT is not suggesting that there

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<sup>6</sup> <http://www.nbr.co.nz/article/health-freedom-groups-win-extension-feedback-natural-health-product-regulations-b-184583>

should be patent protection for natural substances but is highlighting the lack of incentives on manufacturers and others to add an unlisted substance.

34. These factors would stultify the development of the permitted substances list. NZHT understands that in Australia there have been only approximately 30 new ingredients approved since 1990. A limited permitted substances list would deprive consumers of choice and force them to buy online, stifle innovation and damage the financial viability of the industry.

*Black list a much better and risk-proportionate alternative*

35. Given the proven extremely low risk of industrially produced natural health products, an alternative and risk proportionate lynchpin of a credible regime is a blacklist of ingredients. Under a blacklist substances are permitted unless banned or regulated for genuine and credible safety reasons.

#### **Health benefit claims in relation to named conditions**

36. A central objective of the proposed regime is that natural health products are true to claim.

*Objections to the claims regime*

37. The Bill attempts to place unreasonable restrictions on the types of health benefit claims that can be made in that it prohibits all types of ailments and illness about which claims can be made until explicitly approved by the regulator. This is not a risk proportionate regime.
38. The criteria proposed by the Minister to determine a named condition namely, non-serious, self-limiting, suitable for self-management, suitable for self-diagnosis, unlikely to cause serious consequences without health practitioner consultation, are unrealistic and unreasonable and certainly not risk proportionate.
39. This is ironic given the Associate Minister of Health's recent speech to the New Zealand Self-Medication Industry (NZSMI) Association Conference where he said:

*There are challenges posed by, for example, the needs of our ageing population and of the increasing numbers of people with multiple chronic conditions. And they place further demands on health and social services resources. We need to meet these needs in a way that is more efficient, more coordinated and achieves the most from our health dollars.*

*The theme of the conference "Citizen Empowerment through Self Care" is therefore very appropriate. I am pleased that self-care is a focus for NZSMI particularly in the current environment of increasing pressure on our health resources and workforce.*



*Managing these challenges and demands will require greater empowerment of people to care for themselves through education and improved information complemented by public investment.*

*When consumers are empowered to take responsibility for their own care, they move from being passive recipients of care to being engaged in the decision-making about their care. The benefit of empowering citizens is that it involves and encourages interaction and engagement between communities and health care professionals.*

*Self-care also places strong emphasis on the prevention of illness and making the right lifestyle changes or choices.*

40. Many people obtain a diagnosis from a medical practitioner and then choose to self-manage their symptoms and conditions using natural health products. In that context restricting named conditions to those which are self-diagnosed only is unreasonable.
41. The Ministry appears concerned that people would choose to use a natural health product rather than go to the doctor and be prescribed a pharmaceutical drug.
42. This is not a fair concern and is inconsistent with the Minister's endorsement of self-care. First, there is no evidence that this happens to any significant degree. Secondly, it is ironic the Ministry seeks to deprive consumers of the choice of using a low risk natural health products and directs them into using much higher risk pharmaceutical drugs instead.

### **Proposed evidence required**

#### *Objections*

43. There are two points.
44. First, the proposed requirements are unnecessary. There are currently sufficient protections against making unsubstantiated claims in the recently amended Fair Trading Act 1986. Substantial fines are imposed on individuals (\$200,000 maximum fine) and companies (\$600,000 maximum fine) that breach the Act.
45. Secondly, if there is a need to prescribe the evidence requirements, these must be proportionate to the risks posed. There are seven levels of evidence in the Evidence Based Medicine model referred to by the Ministry in the consultation documents, but only the highest three levels are proposed to qualify as acceptable evidence.
46. This is not risk proportionate, nor is it light-handed.
47. The purpose of the evidence is to enable consumers to make informed choices. A light-handed regulator would not use regulation as a means of censorship, especially

in an era when individuals can see for themselves the plethora of evidence by simply googling the internet.

48. As a starting point, a better (and more risk proportionate) approach is to identify a list of sources of accepted claims. To name a few, these would include:
- American Herbal Pharmacopoeia and associated compendium
  - American Botanical Council Monographs
  - Decisions of regulators in jurisdictions recognised by New Zealand (including Australia, Canada, EU Register of Traditional Medicines, European Food Safety Authority)
  - Australia New Zealand Food Standards Authority
  - Australian (TGA) register of medicines
  - British Pharmacopoeia
  - British Herbal Pharmacopoeia and associated Compendium
  - Canada NHP Register of Monographs
  - Codex Alimentarius
  - EU Traditional Herbal Medicine Directive
  - European Pharmacopoeia
  - European Scientific Cooperative on Phytomedicines (ESCOP)
  - German Commission E Monographs
  - Indian Herbal Pharmacopoeia
  - Nga Ringa Whakahaere o Te Iwi Maori Inc
  - Pharmacopoeia of the People's Republic of China, including traditional Chinese medicines
  - United States Pharmacopoeia (USP): US Verified Dietary Supplements
  - World Health Organisation: Monographs on Selected Medicinal Plants.

#### **Code of Manufacturing Practice**

49. NZHT agrees that natural health products must be fit for human use. However what is proposed is not appropriate for several reasons.

#### *Objections*

50. NZHT is opposed to the Code.
51. First, the Code fails to recognise third party audits. The proposed regulations only recognise overseas authorities that **issue** pharmaceutical drug grade GMP. This means that products from countries with GMP standards set by the regulator but audited and issued by third parties (such as the USA, UK, much of Europe, and increasingly Canada) would not be recognised. This would become a major technical barrier to trade.
52. Secondly, it fails to recognise the increasing use of HACCP (as is occurring in Canada even within pharmaceutical drug manufacturing) as a modern risk management tool. It also fails to recognise other codes of good manufacturing practice used widely in the

manufacture of food and dietary supplements. What is proposed would prohibit most natural health products sourced from the US and the UK.

## **Fees**

### ***Objections***

#### *Burdensome compliance costs*

53. The Bill introduces significant and burdensome new compliance costs with no commensurate health benefits to consumers. A good example of this is the notification fee.
54. Small to medium enterprises that sell a high number of low volume products would be unfairly disadvantaged. It is likely that many may go out of business or withdraw a large number of less profitable products as a result of this obligation.
55. The Ministry is suggesting a “low-turnover” exemption could apply to small business, similar to that in Australia. However, in Australia the low-turnover exemption has been set to zero dollars.

#### *The fees unfairly advantage large firms with a small number of high sales products*

56. It is acknowledged that the Bill could benefit those who seek to create a monopoly and reduce competition to expand their market share. The Bill advantages those large firms selling large numbers of a limited number of products. A 1% increase in turnover for a large company would cover any additional costs. The same increase in costs for many small and medium operations may put them out of business.
57. In this way the Bill is highly anti-competitive. A small firm that sells a big range of products but each product has a low turnover, would be significantly disadvantaged. If it has say 500 products the annual notification fees alone would be nearly \$100,000. Some small companies supply 1000 products. At current fee rates that would be \$200,000 annually. Small firms simply couldn't absorb that additional cost.
58. A “light-handed” and risk proportionate regulator would not impose such a burdensome regulatory system, especially on small to medium innovative companies.

#### *Fees represent only a fraction of new compliance costs imposed on industry*

59. The fees to be paid are a tiny fraction of the actual cost that industry would bear complying with the Bill.
60. For example, it has already been noted that the actual cost to prepare a permitted substance application may be \$40,000.

61. The cost to notify products and put information on a website about health benefit claims is likely to be significant, particularly if the notifier has to create a website from scratch. It is estimated to cost at least \$2500 per claim to prepare the information in the required format, get it reviewed, and post it on the website. Some products make several claims and each claim has to go through that process. The cost would be a major technical barrier to making claims and would negate a significant (claimed) reason for the regime in the first place. Most suppliers would continue to avoid making health claims and most consumers would continue to access information via use of Google. Industry has been able to apply for permission to make therapeutic claims for their products for 30 years (under the related product regime in the Medicines Act). However, this process is rarely if ever used because of the similar costs and barriers that arise in the Bill.
62. The cost of preparing an application for a new named condition is estimated to be a few thousand dollars. And likewise putting together a manufacturing licence application, even for companies with existing GMP or equivalent standards.
63. These costs don't exist now and cannot be justified on any rational or risk-proportionate basis. A "light-handed" regulator would not be imposing such burdensome and unwarranted costs.

#### **Labelling**

64. The requirements proposed are excessive and not risk-proportionate.
65. For example, an effective and risk-proportionate labelling regime would not require both manufacturers and notifiers' contact details on labels.

#### **Notification**

66. At the outset, the Ministry wanted a regime that provided them with information about who was in the market and what was in the market. While NZHT had no objection to a simple notification system in the past, what is proposed has become excessive and is not risk proportionate.
67. For example, requiring professionally prepared evidence supporting claims to be provided online as part of the notification system is not risk proportionate. As explained above, it is also extremely costly.

#### **Recognised authorities**

68. What is proposed is not risk proportionate and nor is it "light-handed" for the following reasons.
69. The proposed recognised authorities are primarily pharmaceutical drug regulators rather than natural health product regulators.

70. The proposed recognised authorities for ingredient purposes are only Australia and Canada. That New Zealand is simply proposing to copy two stringently regulated regimes indicates an absence of any robust risk analysis by the Ministry.
71. For GMP purposes, the only recognised GMP certificates are those issued by pharmaceutical drug regulators. GMP certificates that meet approved GMP standards, but are issued by third parties recognised by those same recognised authorities are not being accepted in the proposals. Countries like the UK, USA and many European nations have GMP certification for food supplements that would not be recognised. This means that only companies sourcing product from factories with GMP licences issued by a pharmaceutical drug regulator would be able to be imported into New Zealand. The net consequence is that most products from the USA and England for example, would be prohibited for no good reason.

### **PART 3: BILL BASED ON A FALLACY THAT IT WOULD INCREASE EXPORTS**

72. NZHT understands that a key driver for persisting with the Bill is a belief by the Ministry of Health and the Select Committee that the Bill would result in export growth.
73. NZHT has obtained documents under the Official Information Act 1982 that show that the Ministry has advised the Minister that based on industry estimates the natural health products industry contributes exports of over \$1 billion per year and that exports could grow to \$5 billion per annum by 2025.<sup>7</sup>
74. The Ministry's advice is deceptive and wrong to the extent of the claimed value of current exports, and has no credibility in relation to the claimed export growth.

#### *Export sector not worth \$1 billion*

75. NZHT has not found any reliable evidence of the true value of the natural health product sector in New Zealand, but it is tolerably clear that it is not a \$1 billion plus annual export business. If it were it would be of a similar value to the kiwifruit and wine industries.
76. A 2015 report by Crowe Horwath (in conjunction with MBIE) on the broader natural product sector identified that the natural products industry contributes an estimated \$1.4 b to the economy. That report looked at a large range of natural products (rather than confining itself to natural **health** products) including ingredients, foods, functional foods, and bulk foods exported such as bags of colostrum and drums of honey. The value of exports was reported to be \$285 million among responders and

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<sup>7</sup> Health Report No 20141295

could be extrapolated to \$490 million if non-responders had similar proportions of business.<sup>8</sup>

77. It is emphasised that the Crowe Horwath report was on the broader natural product industry. While the natural **health** product industry is part of this broader industry, it is only a subset of it.
78. An intelligent assessment of the data in the Crowe Horwath report suggests that the natural **health** product sector is about one third of the total of the natural product sector, ie about \$460 million in turnover, including about \$150 million of exports.
79. By way of contrast, Vitaco stated in a recently released prospectus that the New Zealand vitamin and dietary supplement industry was about \$275 million retail.<sup>9</sup>
80. Two points must be emphasised. First, as noted, the wider natural products sector comprises bulk foods, ingredient, functional foods, natural health products/dietary supplements, cosmeceuticals and nutraceuticals. The smaller natural **health** product sector, as defined and regulated by the Bill, is only a component of the natural product sector. Much of the wider sector comprises foods such as colostrum, bulk honey, freeze dried meals and powdered deserts. By way of example, Vitaco's prospectus, registered on the Australian Stock Exchange, notes that only 44% of their turnover is vitamins and dietary supplements. The balance are sports powders and specialist foods.
81. Secondly, the \$285 million (or possibly \$490 million) of exports is for the entire natural products sector and the natural **health** product component of that would be much less. As noted above we have estimated the export value of the natural health product sector as regulated by the Bill to be approximately \$200 million.
82. In summary, while it is not clear what the export value of the natural **health** product sector is, it is most certainly not worth \$1 billion and is more likely to be less than a quarter of that amount.

*The Bill would more likely stifle exports*

83. The NPNZ claim of \$5 billion by 2025 is aspirational and there is no substance to support such a claim. Trade and Enterprise and NPNZ in emails sighted by NZHT have both confirmed as much. Achieving \$5 billion in exports would require compounding growth in excess of 12% for each year over the next decade. There is no evidence to support such exponential growth as being possible.

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<sup>8</sup> Natural Product NZ Survey 2014 Analysis of Results and Key Findings, 4 November 2014

<sup>9</sup> <http://www.vitaco.co.nz/Modules/LSDocumentManager/DocumentDownload>

84. The claim of phenomenal export growth seems to have had its genesis in a submission by NPNZ on the Bill dated 24 February 2012. They state:

*The natural health products industry has grown substantially over the past seven years and is now a significant contributor to the NZ economy.*

*In 2004 the natural product' industry's economic value to New Zealand was \$350 million with \$180 million of that derived from exports. By the end of 2010 the industry's economic value to New Zealand had grown to reach \$1 billion of which over 70% is export-derived. The industry's goal is to reach \$5 billion by 2025, an ambitious goal that incorporates the need for robust regulations and investment/support by the Ministry of Science & Innovation for natural health product companies to undertake more scientific research and clinical trials.<sup>10</sup>*

85. This is misleading as it actually addresses the wider natural products industry, not the smaller natural **health** products sector. This information is also not entirely consistent with the Crowe Horwath report. That report had exports at 35% of the total, not 70% as claimed above by NPNZ. But again the claim of exports increasing is in relation to the natural products sector as a whole. To the extent that regulation is to assist natural health products specifically, the submission refers to enabling more scientific research and clinical trials as being the key.
86. The Bill does not enable more scientific research and clinical trials, and there is no credible evidence as to how it is going to facilitate exports.
87. What is proposed would likely stifle exports, not increase them as claimed.
88. First, the Bill as proposed to be modified by the as yet to be publicly released SOP, restricts the products that can be exported to products containing only permitted substances (that have also been notified). Why the restriction has been imposed is difficult to understand although the Ministry refers to market credibility. Usually an exporter has to manufacture and comply with the overseas country's rules. New Zealand's rules are subservient in most cases.
89. One of NPNZ's largest members, Vitaco, for example, made submissions to the Health Select Committee that such a regime would stifle exports and gave explicit examples related to the Korean market. Following a request from the Health Select Committee, Vitaco wrote to the Chair, Dr Hutchison, explaining that applying the same rules to New Zealand manufactured products destined for the domestic market and New Zealand manufactured products destined for the South Korean market would deny New Zealand manufacturers the opportunity to compete in an export market with

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<sup>10</sup> <http://www.parliament.nz/en-nz/pb/sc/documents/evidence>  
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huge potential for growth. Vitaco gave some particular examples including vitamin B12. They pointed out that the upper limit is 50 ug whereas in Korea it is 2000ug.<sup>11</sup>

90. The 50 ug upper limit for B12 is not based on risk, but on decisions made 30 years ago to restrict consumers' access to healthy and safe levels of the vitamin. There are no known risks associated with any level of vitamin B12, and many countries, including Australia, have no upper limits at all. This is a good example of the Ministry protecting the medical industry interests at the expense of the natural health product sector and consumers.
91. Vitaco made the prescient observation that "We don't want to be creating legislation that has the unintended consequence of muzzling a growing export industry simply because it applies the same rules to products sold in the domestic and export marketplace".
92. In short, the Bill and proposed regulations would make New Zealand products uncompetitive.
93. Secondly, the Bill would stifle exports through the imposition of high compliance costs. Currently amongst importing nations, NZHT understand that New Zealand's system of regulation of these products is regarded more favourably than Australia's. New Zealand is well known for innovative products whereas Australia is not. Why would the Government want to jeopardise that reputation.
94. The Bill is a form of overregulation very similar to the Australian regime and in some case much worse. In Australia the legislation has stifled the export industry and it is logical to expect the same consequences in New Zealand.
95. The complementary medicine export market in Australia is estimated at \$200 million (as at 2013).<sup>12</sup> This represents only about 10% of the total industry output whereas in New Zealand it is approximately 35% although there is great uncertainty about the accuracy of data available for both sectors.

## CONCLUSION

96. The Bill and its proposed regulations are unnecessary and should not proceed for the following reasons.
  - a. The Bill imposes significant and unjustified compliance costs on the industry for no commensurate health benefits.

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<sup>11</sup> [Http://www.parliament.nz/en-nz/pb/sc/documents/evidence/227573 Vitaco-health-supp2](http://www.parliament.nz/en-nz/pb/sc/documents/evidence/227573-Vitaco-health-supp2)

<sup>12</sup> Advancing Market Access for Complementary Medicines In Australia, Report for Complementary medicines Australia, September 2014, p 1



- b. The Bill is being promoted on the basis of factually incorrect advice that it would increase exports. The reality is that it would stifle exports.
- c. The natural health product industry poses de minimis risks and the Bill fails to reflect a key principle of risk proportionality.
- d. The Bill and the proposed regulations are not "light-handed" regulation of a low-risk industry.

*p.p. Lisa Frouse*

Dave Sloan for NZHT