SUBMISSION TO THE

GOVERNMENT ADMINISTRATION

SELECT COMMITTEE

THERAPEUTIC PRODUCTS AND MEDICINES BILL

THE NEW ZEALAND HEALTH TRUST

&

NEW HEALTH NEW ZEALAND

February 2007

SUBMISSION INDEX

SUBMISSION ON THE THERAPEUTIC PRODUCTS AND MEDICINES BILL

EXECUTIVE SUMMARY

1. This submission is made jointly by the New Zealand Health Trust ("NZHT") and New Health New Zealand Incorporated ("New Health"). NZHT is a charitable trust focused on health education and New Health is an incorporated society representing the interests of the New Zealand Health Consumer. New Health currently has over 24,000 members. Both groups are non-profit organisations with no commercial interest in the matters under discussion. Information about both submitters and contact details for them are set out in Appendix I. Both the New Zealand Health Trust and New Health New Zealand wish to be heard in support of their submission.

2. This submission relates to parts 1- 5 of the Bill being the parts that would give effect to the Agreement signed between the Governments of New Zealand and Australia on 11 December 2003 ("the 2003 Agreement").

3. The review of this Bill is somewhat different to most select committee reviews. This is not a situation where there is clear policy to be implemented and the Bill is referred to select committee primarily to work through the detailed provisions to ensure no unintended consequences would arise. In this case the whole concept is flawed, is presented without any clear justification for it and with a marked lack of empirical data to justify the conclusions Government officials present as 'fact'.

4. This Bill would bring into effect an approach to the regulation of complementary healthcare products and medical devices that has never had the support of Parliament, the affected industry at large or New Zealand consumers. The only groups within New Zealand that appear to support the concept are the officials promoting it and a small number of companies seemingly driven by their own self interest.

5. At the outset it must be made quite clear that this Bill, by its own admission, would implement in its entirety and without alteration the 2003 Agreement. Nothing of substance has changed. This approach to the regulation of complementary healthcare products is the same one that was comprehensively and unanimously rejected by the Health Committee in its report of December 2003.

6. Contrary to the recommendations of the Health Committee, this Bill would mean;

    (i) New Zealand health products would be regulated through an off shore entity. While there is provision for joint decision making, the incontrovertible result is that New Zealand will surrender its control of the health products industry

    (ii) complementary healthcare products would be regulated under a pharmaceutical model of regulation despite their unanimous acceptance as low risk, inherently safe, products,

    (iii) the existing Australian system and method of regulation would be extended to cover New Zealand imposing excessive, expensive regulation on low risk products,

    (iv) the ability for tangata whenua to commercialise traditional rongoa would be dictated by an international regulator without any obligation to recognise Treaty Of Waitangi obligations.

(v) the unelected and unknown managing director of the agency would have wide ranging powers to make regulations which would determine significant matters of substance. Given that these matters are left to be spelt out by future regulations (rules and orders), the true nature of the regulatory regime remains unknown at the time of consideration of this Bill.

7. This Committee must not be misled into thinking this issue is about the need to regulate complementary healthcare products. That need is accepted by all of industry and the submitters on behalf of New Zealand consumers. Any emotive presentations about why such products need regulation is therefore irrelevant. Any sensible system of regulation, properly enforced will ensure product safety, clear labelling and provide limits to the claims that can be made. The only question that needs to be asked is what system of regulation of complementary healthcare products will best serve the needs of New Zealand?

8. The system of regulation proposed by this Bill is not the only option, nor does the explanatory note to the Bill properly assess all available options. In our submission the consideration of alternatives is biased having been done from a basis of a pre determined outcome rather than as a true open minded consideration. Viable options for regulation that meet the stated objectives do exist and could be implemented not only in a way that would not prejudice the interests of New Zealand businesses and consumers, but in a way that would encourage increase business investment in New Zealand.

9. Evidence from Australia and from New Zealand industry presented to this and previous committees has and will show that the system of regulation that this Bill would introduce would devastate the complementary healthcare industry in New Zealand, would seriously impede health innovation, would limit consumer options and most importantly would not provide any increase in public safety to justify its heavy compliance burden.

10. This submission supports open trade with Australia and is not opposed to the two countries continuing to work more closely together however the current proposals do not sufficiently protect New Zealand's national sovereignty in this key area. Nor is it accepted that the proposals in the Bill are the only or even the best way to advance the ideals of CER and the Trans Tasman Mutual Recognition Agreement.

RECOMMENDATIONS

11. NZHT and New Health recommend that the recommendations of the Health Committee in its December 2003 report be accepted and adopted by this Committee and this Bill be rejected on the grounds that these recommendations have not be adhered to. The principal recommendations of the Health Committee in this regards being as follows:

(i) that the most appropriate way of governing complementary healthcare products is through the strengthening of domestic regulation

(ii) that an independent risk assessment of complementary healthcare products should be commissioned before promoting a long term regulatory solution

(iii) that the decision making process of any regulatory regime for complementary healthcare products should reflect Treaty of Waitangi obligations

(iv) that any system of regulation treats complementary healthcare products distinctly from both medicines and food

(v) That a small firms impact assessment be applied to any model of regulation

(vi) That any system of regulation of complementary healthcare products should be based on a negative list of restricted or prohibited ingredients.

12. The submitters also recommend that parts 1-5 of the Bill be rejected on the grounds that they do not meet the 5 key principles of good regulatory design set out in New Zealand's *Code of Good Regulatory Practise* being **Efficiency, Effectiveness, Transparency, Clarity** and **Equity**. The onus is on the proponents of the legislation to meet these objectives and they cannot be satisfied merely by bald assertions but instead require proper data and independent, objective analysis, all of which is missing in the present case.

13. In particular it is noted that the 5 principles of the code are not met through failing to demonstrate that the objectives are achieved at the lowest cost and that the cost burden on society is outweighed by the benefits to society. In addition as there has been a failure or unwillingness of the Government to first develop comprehensive policy on the role of complementary healthcare in New Zealand, the regulatory system proposed is incapable of meeting the requirement of achieving desired policy outcomes.

14. On any proper, unbiased assessment, the proponents of this approach have failed to demonstrate that the system of regulation the Bill would impose is in the best interests of New Zealand or that it is demonstrably justified.

15. The submitters recommend that an alternative model of regulation of complementary healthcare products be promoted as detailed in Appendix II.

THE NATURAL HEALTH INDUSTRY

16. There is a distinct lack of official information relating to the complementary healthcare industry in New Zealand. The Government is the body best placed to compile good quality comprehensive data and should have done so as part of its work into the major regulatory transformation it now seeks to impose however this has not occurred.

17. The Bill, its explanatory notes and the documentation surrounding the same fails to provide any empirical evidence about the complementary healthcare industry or the operation of the current system of regulation. Indeed the explanatory notes to the Bill record that New Zealand with its current system of light handed regulation has enjoyed at least as good a level of public safety from complementary healthcare products as Australia. No evidence has been presented justifying the approach now recommended.

18. The Health Select Committee correctly recommended that an independent and comprehensive risk assessment should be carried out in relation to complementary healthcare products. The failure of the Government to do so suggests an awareness that the findings of such an analysis would work against their determination to cede control to the excessive and overly bureaucratic Australian system of regulation.

19. The data available therefore is what has been able to be pieced together from various sources. Independent market research commissioned by NZHT in 2005 indicated that 62% of New Zealanders use complementary healthcare products. By that assessment it is very much a mainstream industry affecting the majority of New Zealanders.

20. Turnover data is equally hard for non governmental bodies to compile reliably however estimates we have seen place annual industry turnover at anything from $300 million upward.

21. Our analysis shows that the industry is characterised by a predominance of small to medium sized businesses. It has previously been indicated that 85% of the businesses in this industry employ 5 or fewer staff and that on average each supplier carries between 300 and 500 product lines. On assessment by turnover however it becomes clear that one company owns two of the largest businesses in this industry (Healtheries and Nutralife) and therefore dominates marketshare. Our information is that that company supports this proposed agency which is not surprising given that it would serve to wipe out so many of the smaller players in New Zealand.

22. The dominance of SME's in this industry justifies the call of the Health Committee that a small firm assessment of the proposal be undertaken. An interesting comparison can be drawn between the recent unbundling of the local loop to which Telecom as the major industry player so strongly objected, but which was forced on them due to its benefit for all businesses in the industry and more importantly the benefit of strong competition within the industry to consumers. Here the fact that the major player may want strengthened regulation needs to be weighed against their own self interest in this outcome and the effect on the New Zealand consumer of effectively limiting competition in this way.

23. Internationally, the emerging trend is that the use of complementary healthcare products continues to increase as consumers take more interest in staying healthy and opt to use low risk, natural alternatives where possible in preference to high risk, chemically based pharmaceutical alternatives.

24. It is suggested that rather than seeking to regulate many such options out of existence, their use and benefits should be focused on and promoted, as appropriate, to improve consumer well-being and take immense pressure of the health budget. This requires a comprehensive and sympathetic study into the use of complementary healthcare products and the developing of robust policies into their use within mainstream health.

25. Whilst good quality regulation of the industry is undoubtedly required, the different and distinct nature of the complementary healthcare products industry must be understood and reflected in the design of an appropriate system of regulation.

26. Complementary healthcare products are not foods and they are equally not medicines. They have different issues to be addressed, work in different ways and have markedly different risk profiles. While at one end of the spectrum there is a fine line to be drawn between some foods and some complementary healthcare products, the same line drawing exercise occurs at the other end of the spectrum with medicines.

27. Furthermore it is increasingly coming to be recognised that the complementary healthcare industry and the pharmaceutical industry are in direct competition in many aspects. To force a smaller and less well resourced industry to be controlled by the same regulator that controls and is predominantly funded by its powerful

pharmaceutical conglomerate competitors is nonsensical and runs counter to basic principles of equity and fairness. In addition those with pharmaceutical backgrounds as many of the regulatory staff would be, tend to have ingrained bias against complementary healthcare products. While some specialists from the complementary healthcare products industry may be appointed, it is submitted they will not be able to achieve much against the predominant tide of pharmaceutically focused management.

GOVERNMENT APPROACH TO THIS BILL

28. As has been noted above the Government has since the release of its 2002 discussion paper, doggedly pushed the trans Tasman agency adopting the Australian system without any genuine interest in reviewing its position or listening the consultation they claimed to be interested in.

29. Despite the unanimous rejection of the proposal and all its key elements by the Health Select Committee the Government pushed ahead to sign the 2003 Agreement, the Minister in charge in fact announcing her intention to do so to the house before the Select Committee report had even been released.

30. It is trite to say that Parliament is the only body that can make laws and anything done without the approval of Parliament has no validity therefore the signing of that 2003 Agreement without the support of the House, or of the New Zealand public, and the work that has been carried out in pursuit of the joint agency since 2003, cannot be allowed to influence the consideration of this legislation in any way.

31. It has also been noted above that the Government has failed to provide data establishing the need for such legislation and detailing with some precision the impact this will have on New Zealand business. This evidence should have been provided as a matter of course. The only justification that has been provided for the new regime is an unsupported allegation that current legislation is “outdated and unsustainable”. Being outdated is only however justification for a review of current laws. That is accepted by all, but it is not in any way justification for leaping into a burdensome, off shore pharmaceutical model of regulation for low risk complementary healthcare products.

32. Insofar as Government proponents of the Bill allege the current system is unsustainable, detailed reading of the explanatory notes show that this claim is in fact only made with reference to the regulation of increasingly complex pharmaceutical products. Whether or not New Zealand is competent to regulate pharmaceuticals is not the focus of this submission, what is critical however is that this provides no justification whatsoever of adding complementary healthcare products into this offshore regime.

33. The only reasons we have seen provided by Government in respect of complementary healthcare products merely support a review of current regulations which we support. Nothing has been provided that justifies this approach over the domestic regulation approach favoured by industry and the Health Committee.

34. One further element of the Government approach to this matter must be noted. In designing this supposedly ‘joint’ agency, wherever there have been inconsistencies between the Australian system of laws and the New Zealand system it appears that the New Zealand system has been forgone without a backward glance in favour of the Australian equivalent. Examples of this include:

(i) Use of Australian legal terminology of rules and orders, in preferences to NZ terminology of regulations

(ii) Watering down of the NZ privacy principles in favour of the Australian standards.

(iii) Weakening the existing NZ disallowance protocols by removing the ability to reject in part or amend in keeping with the Australian approach.

(iv) Adoption of higher penalties than is usual in NZ to meet existing Australian levels.

(v) Excluding regulations from the NZ Interpretation Act 1999

(vi) The codifying of what have always been common law defences to ensure equivalency with Australia

(vii) Broadening the range of enforcement options to reflect the Australian approach.

35. This complete adoption of all things Australian highlights our concerns about the lack of a proper analysis of how the countries can work more closely together while still maintaining the proper integrity and independence of each sovereign state. A joint agency in name with supposed joint decision making at the highest levels begins to look much more like a complete abdication of authority and control with some trappings of equality maintained for the sake of appearances,

STRUCTURE OF THE PROPOSED AGENCY

36. The explanatory note and Bill itself confirm that the agency that would be created if this legislation were enacted is exactly the same agency outlined in the 2003 Agreement. Any supposed "concessions" to New Zealand industry can only be intended to be made in rules (regulations) which are of course as yet unconfirmed and can be changed at the stroke of a pen without effective recourse to the New Zealand Parliament [see comments on disallowance issues below].

37. While the Ministerial Council at the head of the governance ladder is staffed by the two Ministers of each country, what is indisputable is that New Zealand can do nothing on its own initiative unless Australia chooses to consent. No matter how it is dressed up that is a significant limit on the control of the industry the New Zealand Parliament currently enjoys.

38. Further the respective bargaining positions of the two countries must be taken into account is assessing how the 'joint' decision making is likely to occur in practise. Given the success the Australians appear to have had in requiring New Zealand to accept their system in all respects including our adoption of related legal structures [see above], very little confidence can be had in New Zealand's ability to truly be an equal voice within the Ministerial Council.

39. It should also be noted at this point that the 2003 Agreement which would be implemented by this Bill, specifically provides for the introduction of other countries into the scheme which would of necessity see New Zealand's voice diluted. The Bill makes no reference to the introduction of further countries needing to come back to the New Zealand Parliament meaning that Parliament would have no opportunity to

consider the implication of the same on its control over the agency. In our submission this is an unacceptable usurping of the role of Parliament.

40. Sitting directly under the Ministerial Council and appointed by them is the Board of the Agency which is staffed by up to 5 members, one of which is the managing director of the agency, one of which is the chairperson, a New Zealand appointee, an Australian appointee and someone with broad commercial expertise. Therefore it is entirely possibly (and likely) that New Zealand would only have one representative on the 5 member board.

41. The board in any event specifically does not have control of the regulatory functions of the agency and so have no use at all as a check and balance on the unfettered regulatory power of the managing director. While the Board must present a statement of intent and annual report to the minister each year who then tables it in the house, as the Board has no control over regulatory matters we question the usefulness of this except as a financial control mechanism. The Bill in any event makes no provision for a remedy for Parliament should it be unhappy with any report presented to it.

42. The managing director is, in a practical sense, the person who determines the regulatory environment for all therapeutic products in New Zealand and Australia. He or she has the power to make orders which have the force of law in both countries and the scope of those orders is such so as to determine the day to day environment in which New Zealand businesses will operate.

43. It must be remembered in the consideration of the Bill that those orders that are of primary importance to industry and therefore to consumers are not only unknown in their final form at this time, they can be changed at will by the agency.

44. The enactment of this Bill would involve a complete abdication of control to this agency and once that control is gone the Parliament of New Zealand would have no direct control over the regulation of therapeutic products except via the limited disallowance regime [comments below]. In that respect establishing this agency is tantamount to signing a contract before reading it and effectively would be simply telling the managing director to do whatever he thinks best.

DECISION MAKING IN THE PROPOSED AGENCY

Rules and Orders

45. As is referred to above rules and orders made by the agency would have the force of law in both countries equivalent to regulations. Rules are made by the Ministerial Council and orders are made by the managing director however both are of equal status in law.

46. The width of delegated decision making under the proposed agency is extremely concerning. It is well settled that Regulations should only be used for matters of details with significant matters of policy being reserved exclusively for primary legislation and subject to the full and unlimited scrutiny of the House. In this instance however the primary legislation is used merely to set up an off shore agency and hand all control to it. It is that body that is then empowered to make all policy and costing decisions and has the power to impose these with the force of law. In our submission that is an unacceptable manipulation of the system of delegated decision making and the Bill should be rejected on that ground alone.

Disallowance

47. While there is a system of disallowance provided for in the Bill it is not the system the applies generally in New Zealand under the Regulations (Disallowance) Act 1989. In order to once again comply with Australia, the system is watered down with the most concerning change being the removal of the ability for the house to consider each rule separately and the removal of the ability of the house to reject in part or amend the rules.

48. As a consequence when an omnibus collection of rules is presented, Parliament will have an all-or-nothing choice to make. To object to one rule it would need to throw the whole lot out which is likely to be reluctant to do.

49. In addition a change to procedure means that if a disallowance motion is put by a Member of Parliament (not being a member of the regulation review committee) it will fail merely for not having been called within 21 sitting days of being put. That is a change from the New Zealand system where there is no such time lapse provision and is significant given that Government is likely to control the business of the house and could conceivably manage this provision to their advantage.

Reviews and appeals

50. For most decisions of the agency the only recourse to an affected party would be to bring judicial review proceedings which is not only prohibitively expensive in most cases, but also by its limited grounds of consideration, the most difficult sort of proceedings in which to prove your case. It is not an appeal against a decision where all factors can be considered.

51. The only matters which have a right of appeal are the decisions of the agency in regards the granting, alteration or suspension of a product approval. In those cases however firstly a company must comply with any internal review processes the managing director sees fit to create and only once that has been completed (being an open ended period of time), the business may apply to the agencies own merits review tribunal in New Zealand or Australia.

52. The merits review tribunal structure as laid out in this Bill is so fundamentally flawed as to be not just of no use but actually likely to cause further hardship to an aggrieved applicant due to the time delay and costs of having to comply with this process before progressing to a genuinely independent review if that is even permitted.

53. The biggest concern with the review tribunals are that its members are appointed by the same Ministerial Council that sits at the head of the agency. There is as a result a total lack of independence of appointment making the agency the effective judge in its own court. Furthermore there are no controls on the time in which the review process would be completed and it is clear that the original decision of the agency would stand unless and until overturned by the Tribunal. Even if an objective decision could be obtained, this could result in a delay of many years whilst the applicant could have been driven out of business by a baseless decision of the agency.

54. Also worthy of note in regards the review tribunal processes is that the Australian Attorney General has the ability to demand that New Zealand review hearings are transferred to Australia and also that reasons for the eventual decision are not released. No reciprocal powers are given to the New Zealand Attorney General.

55. Appeals to the High Court from Review Tribunal decisions are only permitted on matters of law which means that there is no right to appeal to an independent body based on inappropriate or patently wrong findings of fact. Even in the narrow cases where appeal to the High Court is possible the costs and time delays will be further exacerbated and is unlikely to be within the resources of most small to mid sized companies.

Enforcement:

56. This is one of the most concerning areas in the Bill for many reasons. Every system of regulation needs to have penalties and fines to enforce it however they need to be set so as to be effective without being unjustifiable and most importantly there need to be arrangements to ensure they are applied fairly and even-handedly.

57. In the Bill explanatory note the Government admits that the penalties imposed by the Bill are high by NZ standards and gives as the only justification for this that it is done to match Australia. Here like in many other places the possibility of Australia adapting to our system was apparently not considered.

58. The Bill provides for a number of offences based around not complying with the authority's rules. In each case there are several levels of the offence; civil penalty offences, summary offences, indictable offences and strict liability offences.

59. Strangely, supposed 'civil' penalty offences carry the highest potential penalty, are the easiest for the authority to prove (not including any need to prove any intention) and worst of all use a lower standard of proof that has never, to our knowledge been applied to prosecutions of this type. This runs contrary to all usual notions of prosecutions and procedural fairness.

60. Another serious concern is the ability of the authority to issue "non compliance notices". These can be issued up to 12 months after you are alleged to have committed an offence for up to $550,000 for the company plus $55,000 for each director and senior manager. If you pay these amounts within 28 days nothing further comes of it. If you don't pay you get prosecuted. There is no recourse against the decision to issue such notices to the review tribunal.

61. We wonder how these non compliance notices can enhance consumer safety when they involve no admission of guilt and carry no record with them for future issues. Further it seems to us that these contain an enormous and uncontrollable amount of discretion that could allow agency staff to selectively use such notices and set varying fee levels depending on their relationship with different organizations. In many cases the prospect of the time and costs of full prosecutions may well mean that companies who may feel they have done nothing wrong are pressured to pay on such notices to remain viable. Other than judicial review, there is no accountability of the agency if it issues such notices without a proper basis for doing so.

62. Other concerns include

    (i) The defendant having to provide evidence to the authority before the trial of certain defences but the authority not having to disclose its own evidence relating to that until during the trial. (cl.34)

    (ii) A ban on judges taking into account any efforts by the defendant to ensure harm was prevented in sentencing (cl.31)

(iii) A certificate by the Managing Director being sufficient evidence of certain things in New Zealand but not in Australia (cl.35(1)(l))

(iv) The authority having 6 years to lay charges instead of the usual 6 months that applies to summary offences in NZ (cl.30)

(v) As well as a company being liable for fines up to $5,500,000 each director and each member of a companies management team can also be liable for fines up to $550,000 and up to 5 years in jail. (cl.46 – 48)

(vi) The agency staff have full search and seizure powers based on them holding a reasonable belief of wrongdoing. (cl.98 on)

Advertising

63. cl.62 of the Bill contains a detailed list of the types of advertisement it is an offence to publish and once again imposes fees of up to $5,500,000 for breach for a company and up to $50,000 for each director or manager. In addition however the Bill provides in cl.63 that the rules may require pre-vetting of all advertisements if the rules decide to impose this obligation and further heavy penalties if this is not done. Given the extensive restriction in cl.62 the additional obligation to have all ads pre approved at additional cost to business is a totally unnecessary layer of compliance costs with little discernable public safety benefit.

INAPPROPRIATENESS OF A PHARMACEUTICAL MODEL

64. We have already set out some of the differences between the pharmaceutical industry and the natural health industry detailing the different risk profiles and the fact that they are in many way competing industries. All of this argues against their being regulated by the same body.

65. In addition to these factors the financial realities of the two industries are vastly different. In the pharmaceutical industry new drugs, once developed, can be patented providing the maker with a statutory monopoly for a period of years in which they can more than recoup their investment in the development and compliance costs for that drug. Therefore high compliance costs do not unduly impede innovation. In the complementary health sector however patents are not available for most products due to their natural ingredient basis. As a result any increase in the costs to market significantly affect businesses willingness to spend money on research and development and proving “new’ ingredients because as soon as a product is licensed then every other manufacturer is free to bring out their own version and compete meaning that those development costs are not recovered. A pharmaceutical system therefore would significantly impede innovation in complementary healthcare.

66. Another example of the inappropriateness of a pharmaceutical model relates to the level of penalties. It has already been shown that the average business size between the two industries is at the opposite ends of the scale. The penalties required to properly incentivize a multi national to comply with the rules is markedly different from what can fairly be imposed on a much smaller business. Further the potential for mass harm from pharmaceutical products is many many times greater than for low risk complementary healthcare products and this should be recognised in the appropriate penalty levels.

67. This issue relating to appropriate penalty levels takes on increased importance when it is remember that the penalties can be imposed by the agency staff without external proving of a case by way of non compliance notices and that combined with the cost of challenging decisions are unfairly onerous on small businesses.

68. For the above reasons and those set out earlier there is not an option of watering down the enforcement and industry accountability measures in the agency to better reflect fair regulation of complementary healthcare products as this would provide far too low a level of penalty for pharmaceutical companies. In fact the current penalty levels as set out in the Bill are already, it is submitted, too low to seriously concern the biggest of multinationals.

IMPACT ON NEW ZEALAND INDUSTRY

69. Other submissions to this committee detail the extent of the likely compliance costs on New Zealand industry. In this submission we want to highlight that whatever the cost levels are assessed at currently and whether or not there is some rebating of initial annual fees, all of these matters are dealt with under regulation and so can and likely will worsen considerably once the agency is in full control. This committee should therefore, it is submitted, apply a worst case scenario to compliance costs rather than a best case one.

70. Another point that must be made in respect of costs is that the total cost to industry is far more than the line item products approval fees which are under discussion for some initial rebate. Businesses in Australia report that the biggest costs to them are often indirect ones such as:

    (i) the costs of using necessary consultants to comply with regulator standards

    (ii) The costs of every change to regulatory standards such as new computer equipment and software, new labelling costs, new advertising costs, finding new suppliers etc.

    (iii) The costs of as many unwarranted audits of you and your suppliers as the regulator decides to impose regardless of whether or not any areas of non compliance are found

    (iv) The costs of delays to market as applications taken unreasonably long periods of time and without recourse to challenge delays.

71. Under a system such as this most of the products that are lost from New Zealand shelves are predicted to be lost not because of a failure to meet any product standards but because of the economic viability of the product line or the company promoting them being lost due to the unnecessary compliance burden.

72. Once again without set fee levels and good industry information having been supplied, the Government is in no position to properly assess the compliance cost burden on New Zealand industry but we predict it will be considerably higher than the figures outlined in the regulatory impact statement. We note that the authors of that statement say themselves that they really can't be sure due to a lack of data. In our submission it is unacceptable to promote legislation without clear details of the cost to business based on reliable and disclosed data.

IMPACT ON NEW ZEALAND CONSUMERS

73. The NZHT and New Health are involved in this process at considerable cost because of grave concerns that far from advancing the public health and safety of New Zealanders, the proposals in the Bill would make New Zealand consumers significantly worse off.

74. The explanatory note to the Bill proves what we have always said which is that for all its heavy handed autocratic regulatory systems Australia has achieved no more public safety from complementary healthcare products than New Zealand's light handed approach has.

75. It is not in the best interests of New Zealand for competition in such an important industry to be decimated due to overly burdensome regulations, it is not in the best interest of New Zealanders for product choice to be lost to them not because of safety issues but because compliance costs make continuing with those products uneconomic and it is not in their best interests if remaining products become much more expensive as compliance costs are passed on to them.

76. At the end of the day it is submitted that consumers have an inalienable right to choose their health options and the role of government should be limited to concerns about safety and ensuring consumers are not misled. Those concerns can be properly addressed by simple domestic legislation rather than adopting a big brother approach.

REGULATORY ALTERNATIVES

77. New Zealand needs a robust system of regulating complementary healthcare products. Of that there is no debate. The starting point for such a system however is to gather good quality data about the industry, and its products including comprehensive risk assessments. Only once that is done policy can be developed relating to the place of complementary healthcare in New Zealand and the system of regulation that best meets New Zealand's objectives in that regard.

78. Trying to design a shared system with Australia before New Zealand's objectives are defined is not sound.

79. Areas of concern need to be highlighted and then addressed, in the absence of the Government having done this we have identified the areas of concern from the information put out by Medsafe and the Minister. From these areas of stated concerns a proposed model of regulation has been developed which addresses all such concerns and still meets the needs of industry without compromising in anyway public safety.

80. This model was developed in 2003 and presented to the Health Select Committee as part of their hearings in this matter and the key components of the Health Select Committee's recommendations as to what a system of regulation should include are all provided for in this model. The model synopsis is attached as Appendix II.

81. There is no basis for asserting that domestic regulation is unsustainable or that the compliance costs would be greater than under the ANZTPA proposal as set out in the Bill. The compliance costs of a domestic system depend of course on the nature of that system and the attached was prepared and costed to show that a sensible and robust system can be developed and instituted at a very low level of cost to business and in a way that encourages compliance and does not limit innovation.

APPENDIX I: DETAILS AND CONTACT INFORMATION OF SUBMITTERS

NEW ZEALAND HEALTH TRUST

Objects of the New Zealand Health Trust.

The Trust is established for educational and charitable objects and purposes within New Zealand only. In particular the Trust is established:

(a) To commission research into health issues and, in particular, health care products, devices, practices and services within New Zealand by all such means as may be thought advisable;

(b) To acquire information in relation to health conditions, afflictions and diseases to enable a better understanding of the health needs of the community and any treatment or prevention recommended as a result thereof;

(c) To procure from and to communicate to any other organisation or body whether incorporated or not whose objects are similar to those of the Trust such information as may be likely to assist or forward any of the objects of the Trust;

(d) To stimulate, co-ordinate and support research within New Zealand, into the cause, prevention, alleviation and cures of health disorders and to obtain and disseminate information on any aspects of the foregoing;

(e) To encourage and provide opportunities for persons and corporate bodies within New Zealand to take an active interest in the funding of complimentary health care products, devices, practices and services and general health research for prevention, diagnosis and treatment;

(f) To inform and educate persons and publicise progress on the research of the Trust;

(g) To work in co-operation with the New Zealand health services and the health care providers in New Zealand;

(h) To provide registering, monitoring and reporting programmes and processes on health care products, devices, practices and services;

(i) To raise and employ funds for any educational or charitable purposes within New Zealand authorised by these objects;

(j) To promote the recognition and support of the Trust's objects by Government, local authorities, other statutory bodes, the New Zealand business community and all persons living in New Zealand generally;

(k) To assist with the provision of equipment, venues, information sources and material necessary for the conduct of training programmes, research and the promotion of these objects;

(l) To hold seminars, tutorials and lectures and to demonstrate the research to promote the aims and objects of the Trust to the community generally.

Contact details

P O Box 34-057
CHRISTCHURCH Contact Person: David Sloan

PH 03-351 9807 FAX: 03 351 7993

NEW HEALTH NEW ZEALAND INCORPORATED

New Health New Zealand is an incorporated society formed in 2005 as a consumer group. New Health currently has in excess of 24,000 members and is committed to;

- Creating a system focusing on best health outcomes for consumers
- Demanding accountability from the health system and health providers
- Promoting health not selling sickness
- Providing a single coordinated approach to health regulation
- Supporting businesses that put consumers first
- Change the focus from symptom control to addressing underlying causes
- Encouraging health innovation

Contact Details

C/- Mortlock McCormack Law
P O Box 13 474
CHRISTCHURCH Contact Person: Amy Adams

PH 03 353 5774 FAX: 03 377 2999

APPENDIX II: SYNOPSIS OF THE PROPOSED MODEL FOR REGULATION OF DIETARY SUPPLEMENTS IN NEW ZEALAND

[attached]

PROPOSED MODEL FOR THE REGULATION OF DIETARY SUPPLEMENTS IN NEW ZEALAND

SYNOPSIS

CREATED AND PRESENTED BY

THE NEW ZEALAND HEALTH TRUST

SEPTEMBER 2003 &
REVISED FEBRUARY 2007

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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 review of the way in which Dietary Supplements are regulated in New Zealand and strongly opposes the Therapeutic Products and Medicines Bill insofar as it would create a Joint Trans-Tasman agency responsible for the regulation of all therapeutic products including pharmaceutical medicines, medical devices and dietary supplements (ANZTPA).

The arguments advanced by the Trust in opposition to the ANZTPA 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's website www.nzhealthtrust.co.nz;

- 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 ANZTPA.
- 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").
- March 2004 – Briefing paper to the Health Select Committee on the Treaty
- April 2004 – 2nd submission to the HSC
- May 2004 – 3rd submission to the HSC
- September 2004 – Response f the NZHT to the Government response to the HSC report
- December 2005 – Summary of Concerns
- February 2007 – Submission to the Government Administration Select Committee

For further information on the ANZTPA proposal or the basis for the Trusts opposition to it please contact the Trust. For present purposes it is sufficient to record that the ANZTPA 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 ANZTPA 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 ANZTPA approach.

The Trust has completed the framework for this alternative model, has built a working model of the central website and has undertaken initial steps towards the remaining 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 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.

The Trustee
The New Zealand Health Trust
P O Box 34-057
CHRISTCHURCH

ph: 03-3519807
fax: 03-3517993
email: **nzhealthtrust@ihug.co.nz**

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 ANZTPA 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 business unit 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 ANZTPA. 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 theses 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 imposes 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 a key element of the proposed regulatory model.

The claims guide 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 operational to a concept testing stage. 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.

When 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 ANZTPA 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 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 ANZTPA approach.

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

September 2003.