SUBMISSION ON THE DISCUSSION PAPER:

"PROPOSAL FOR A TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS"

BY THE

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SUMMARY

1. This submission is made on behalf of the New Zealand Health Trust ("**NZHT**"). NZHT was recently formed to represent the interests of the complementary healthcare community, which includes consumers, practitioners and manufacturers. The objects of the NZHT are set out in Appendix I.

2. The discussion paper *A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products* ("**the Discussion Paper**") sets out a proposed regulatory regime for New Zealand and Australian medicines, complementary healthcare products and medical devices. The focus of this submission addresses the issues relating to complementary healthcare products ("**CHPs**").

3. The Discussion Paper does more than its title suggests and in fact has two objectives:

   (a) Development of a new regulatory regime for CHPs in New Zealand; and

   (b) To resolve the special exemption for therapeutic goods under the Trans Tasman Mutual Recognition Agreement ("**TTMRA**").

4. These are two very separate matters that should not be collapsed and progressed together.

5. The Discussion Paper proposes a new Trans Tasman regulatory regime and a new regulatory agency without following proper principles of policy development and design of a regulatory regime. There is no empirical evidence about the operation of the current regulatory regime or systematically describing the CHP industry. There is no analysis of whether there is a policy problem arising from the status quo. Indeed the new Trans Tasman body appears to masquerade as a policy solution in search of a problem.

6. What compounds the situation is that the proposal in the Discussion Paper ignores the Ministerial Advisory Committee on Complementary Healthcare which was established to provide advice on complementary healthcare issues. With respect, the Discussion Paper arbitrarily overrides that process. This is an unacceptable approach.

7. The proposal in the Discussion Paper completely preempts the policy work that should first be completed to define and state New Zealand's policy on CHP and complementary health generally. Only after that can the Government ascertain whether there is a problem with the current regulatory framework which requires a solution. The approach is one of "putting the cart before the horse".

RECOMMENDATION

8. We recommend that the proposals in the Discussion Paper relating to CHPs be suspended immediately. The development of a regulatory regime for CHPs in New Zealand should be deferred until New Zealand's policy on complementary healthcare has been determined. Once the policy is clear the issue of the special exemption for complementary healthcare products under the TTMRA can be

addressed. If a new regulatory regime is needed, it should be developed once we know what the problems are, and the nature of the industry the Government is seeking to regulate.

LACK OF NEW ZEALAND POLICY ON DIETARY SUPPLEMENTS, COMPLEMENTARY HEALTHCARE PRODUCTS, AND COMPLEMENTARY AND ALTERNATIVE HEALTH

9. New Zealand does not currently have a clearly defined policy on CHPs and complementary and alternative health. The absence of a defined policy position makes it difficult to ensure that New Zealand's interests are protected in resolving the special exemption under the TTMRA as it relates to CHPs.

Principles of Developing Good Legislation

10. A decision to develop policy and enshrine it in new legislation should not be taken lightly, as development and implementation involves significant compliance costs for the business community. These costs include the costs of development, and the time and expense of those enforcing, administering, implementing or complying with the new legislation.

11. The first essential step of developing new legislation is to define and state the policy objectives. In other words, what is the mischief that is being addressed? Only after there is clarity about the problem can we determine an appropriate solution. If no problem is established, then there is no need for regulatory reform.

12. The *Code of Good Regulatory Practice* published by the Ministry of Economic Development sets out 5 principles for good regulatory design:

    (a) **Efficiency:** Adopt and maintain only regulations for which the costs on society are justified by the benefits to society, and that achieve objectives at lowest cost, taking into account alternative approaches to regulation.

    (b) **Effectiveness:** Regulation should be designed to achieve the desired policy outcome.

    (c) **Transparency:** The regulation making process should be transparent to both the decision-makers and those affected by regulation.

    (d) **Clarity:** Regulatory processes and requirements should be as understandable and accessible as practicable.

    (e) **Equity:** Regulation should be fair and treat those affected equitably.

13. The proposal in the Discussion Document fails to meet the first essential step in developing legislation, in that the policy objectives for CHPs in New Zealand have not been defined and stated. In terms of the *Code of Good Regulatory Practice*, there has been no systematic analysis of the New Zealand CHP industry, which means that no assessment of efficiency or effectiveness as defined in the Code can be undertaken.

New Zealand's Lack of Policy on Complementary Healthcare Products

14. We understand that a "Healthcare and Therapeutic Products Bill" has been on the legislation programme of the Ministry of Health ("**the Ministry**") throughout the 1990s. However it has not featured high enough to rate a priority for policy development and drafting resources. At page *xxi* the Discussion Paper makes it clear that the proposals for a "Healthcare and Therapeutic Products Bill" **no longer have any standing** given the Government's in-principle decision to progress the joint agency proposal. However, that statement itself should not have any standing since there is as yet no Government policy direction with respect to CHPs.

15. This leaves New Zealand in the unenviable position of developing its policy on CHPs, while at the same time working to harmonise the New Zealand position with Australia. By contrast the Australian position appears to be well settled. The Discussion Paper amply demonstrates this. The Australian system is described in clear terms. Should the proposal in the Discussion Paper not proceed, Australia will continue with the regime it currently has in place. The discussion about New Zealand instead talks of the need to develop proposals for new legislation in New Zealand.

16. The risk inherent in this approach is that, in the absence of a clearly defined policy position for New Zealand, the Australian system is all to easily seen as a ready made solution. Harmonisation based on Australian policy settings means minimal disruption to the larger Australian beuracracy and CHP industry, and might help achieve the objective of harmonisation under the TTMRA. However, this outcome does not achieve the objective of developing a regulatory regime for CHPs that best meets New Zealand's needs.

17. To ensure New Zealand's interests are protected, New Zealand must first complete its own policy review of CHPs and the place of complementary and alternative healthcare in New Zealand. Only then should it look to address the issues raised by the special exemption under the TTMRA for therapeutic goods to the extent that it relates to CHPs. This includes systematically gathering data and empirical evidence on the operation of the current regime, the nature of the New Zealand industry and a wide ranging survey of international trends. This will provide a transparent base on which to develop changes to the regulatory regime, if this is found to be necessary.

18. Until New Zealand has a policy position regarding how CHPs should be regulated in this country, a meaningful assessment of how to resolve the special exemption under the TTMRA cannot be undertaken.

19. The Minister of Health has appointed a Ministerial Advisory Committee to advise on issues to do with complementary and alternative health, and specifically to provide advice in areas such as regulation, consumer information needs, research, and integration. The work undertaken by that Committee and its findings may impact on the final design of any regulatory regime. It should be allowed to complete its review and present its findings to inform the design of any new regulatory regime for New Zealand. In the meantime, discussion of CHPs in the TTMRA context should be suspended.

Ministerial Advisory Committee on Complementary and Alternative Health Care

20. The Ministerial Advisory Committee on Complementary and Alternative Healthcare ("**MACCAH**") was established in June 2001 under section 11 of the New Zealand Public Health and Disability Act 2000.

21. The purpose of the MACCAH is to advise the Minister of Health on issues to do with complementary and alternative health, and specifically to provide advice in areas such as regulation, consumer information needs, research and integration. The MACCAH is funded to run until June 2004.

22. The terms of reference for the MACCAH state:

> The key tasks for the Committee are:
>
> (a) to provide **information and advice to the Minister on complementary and alternative healthcare**;
>
> (b) to provide advice on how complementary and alternative healthcare can improve outcomes in the priority areas signalled in the New Zealand Health Strategy;
>
> (c) to provide advice on the need, or otherwise, to **regulate complementary and alternative healthcare practitioners** in order to **protect consumers** who use complementary and alternative healthcare;
>
> (d) to provide advice on consumer information needs and, in particular, advice on the benefits, **risks** and costs of complementary and alternative therapies;
>
> (e) to review overseas evidence-based research, identify priorities for the development of New Zealand evidence-based research on the safety and efficacy of specific complementary and alternative therapies and support the development of guidelines;
>
> (f) to provide advice on **whether, and how, specified complementary and alternative health practitioners should be integrated into the mainstream system**. (Emphasis added)

23. The MACCAH programme involves broad ranging information gathering processes, consultation processes and development of recommendations relating to complementary and alternative healthcare. However, our understanding is that the MACCAH has to date focused on paragraphs (c) and (f) of its key tasks regarding the regulation of complementary and alternative healthcare practitioners.

24. Complementary and alternative health and associated products are a growing and important part of the response to the objectives and goals for the New Zealand health system. In fact, throughout the world there is a growing recognition of the value of complementary healthcare. The World Health Organisation ("**WHO**") recently released its *Traditional Medicine Strategy 2002 – 2005*, which has as the first step assisting members to develop their policy on complementary and alternative healthcare. Subsequent to that first step, the next stages of development are providing mechanisms to promote

safety, efficacy and quality of CHPs, increasing availability and affordability, and to promote the sound use of CHPs.

25. New Zealand must develop its policy on CHPs and complementary and alternative health before determining what regulatory interventions might be required. Promoting a regulatory framework before the policy has been settled simply ignores the first essential step of good law making.

26. Paragraphs (c) and (f) of MACCAH's list of key tasks refer to the regulation of practitioners. The MACCAH appears to be targeting the issue of practitioners. This leaves a gap in the policy development process with no equivalent systematic consideration being given to CHPs.

27. However, the other aspects of the MACCAH work programme and key tasks refer to wider information gathering and the place of complementary healthcare in the New Zealand health system. This wider work regarding the place of complementary health in New Zealand should inform the decisions about the availability and regulation of CHPs, which are an essential part of that wider complementary health sector.

28. NZHT is concerned that if the proposal in the Discussion Paper is advanced prior to the completion of the MACCAH work programme and the determination of New Zealand's policy on CHPs, any changes in New Zealand's regulatory framework may simply get it wrong. The changes would have to be negotiated through the treaty process and reflected in legislation in both countries. Before any further steps are taken to commit New Zealand to a particular regulatory framework, New Zealand must be sure that its policy is right.

29. A Ministerial Advisory Committee has been appointed, and it is mandated to carry out public consultation and to listen to the views of New Zealanders. It will report and make recommendations on the regulation of practitioners, but its key tasks also include providing information on complimentary healthcare, and how it can improve outcomes signaled in the New Zealand Health Strategy. This information will provide the wider policy context in which the development of a regulatory regime for CHPs should take place. A regulatory response prior to the Committee's report and recommendation is premature.

Database on Safety and Efficacy of Complementary Healthcare

30. In addition to MACCAH, the Government also announced as part of Budget 2002 $600,000 in new funding over the next four years to look into the safety and efficacy of complementary and alternative healthcare products. The objective of the commitment of funding was to create an online database to improve New Zealander's access to overseas research. The target users included practitioners, consumers, independent researchers, policy makers and other medical practitioners.

31. This initiative is very important given the importance of the knowledge regarding the use of dietary supplements and complementary healthcare products being the key to unlocking their potential.

32. This initiative is also very relevant to a risk-based approach to regulating complementary healthcare products. By providing a level of education and understanding to people who choose to use these products, the risk of "snake oil merchants" deceiving consumers is essentially eliminated. The information necessary to counter unethical operators must be readily available to all members of the public.

Timetable of Policy Initiatives in the Complementary Healthcare Sector

33. These developments show a worrying lack of co-ordination. We have put together the timetable for MACCAH to develop New Zealand's policy in the complementary health sector together with the TTMRA timetable. It looks as follows:

June 2001	MACCAH established with detailed work programme.
May 2002	Funding for Database of information on CHPs announced.
June 2002	*A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products* Discussion Paper released.
2 August 2002	Closing date for submission on Discussion Paper.
Late 2002	Report back to NZ/Australian Governments for policy approval on Discussion Paper proposal.
2003	Conclusion and signing of treaty.
2003	Passage of legislation establishing the Agency.
2004	Treaty and legislation come into force.
Mid 2004	Agency commences operation.
June 2004	MACCAH concludes its work programme and reports to the Minister of Health.

34. This timetable demonstrates graphically the absurdity of the current situation. Applying the principles of good policy making, the final action on this timeline should be the first. In addition there is a policy vacuum in that no systematic consideration is being given to New Zealand's policy on CHPs. A major initiative is being advanced before any policy decisions are made regarding the framework for elements of the complementary health sector. There is a lack of a co-ordinated policy. This approach is also inconsistent with the WHO recommendations.

35. The current approach quite clearly has put the cart before the horse. It has all the hallmarks of policy predetermination and failure to bring a genuine open mind to decision making.

EMPIRICAL EVIDENCE ON THE NEW ZEALAND COMPLEMENTARY HEALTHCARE PRODUCTS INDUSTRY

36. There is no official systematic review of the nature and size of the New Zealand CHP industry and how it is operating under the current regulatory regime in New Zealand. While the Discussion Paper consultation process will reveal more details about the make up of the industry, NZHT submits that it is vital

before any definitive decisions are made about the regulatory regime for the CHP industry that a comprehensive survey and analysis of the industry be undertaken. The information that needs to be collected includes:

- Characteristics of industry participants;
- Range of products that are available to New Zealand consumers;
- Economic value of the CHP industry and its growth potential;
- Healthcare benefits generated by the CHP industry, and its impact on achieving the objectives of the New Zealand Health Strategy; and
- Public health risks posed by the CHP industry.

37. This task would be the first to be undertaken as part of the policy development programme for CHPs.

38. The New Zealand Natural Nutritional Foods Association ("**NNFA**"), the largest industry group, has indicated that the industry comprises approximately 200 participants, of which the majority are small to medium sized manufacturers and suppliers. Approximately 85% of the businesses employ 5 or fewer staff. The number of product lines carried by each supplier is generally 300 – 500. This is consistent with the Canadian findings from the extensive work carried on CHPs, which identified that the Canadian industry was comprised of small and medium sized businesses that are labour intensive operations.

39. The value of the New Zealand industry is estimated at NZ$210 million in retail sales through a range of outlets including health food shops, pharmacies, supermarkets and complementary health practitioners.

40. While a general picture of the industry is available from such information, it is necessary in developing policy and regulatory proposals for the complementary healthcare industry to conduct a systematic survey of the industry.

41. The Australians in this regard have the advantage of an accurate current picture of what products are available in Australia and who is supplying those products from the fact that they currently operate registers of industry participants and products currently available in their market.

42. This information is critical for a number of reasons. Without an accurate picture of the industry the most fundamental question of policy development and regulatory design – "What is the mischief?" – cannot be adequately answered. Assertions that there is a public health risk associated with CHPs in the Discussion Paper are not supported by any empirical evidence. Evidence of what those risks might be is required before an appropriate policy position and regulatory regime can be designed.

43. NZHT acknowledges that there have been individual cases of products raising public health concerns. For example products such as Lyprinol, K4 and other herbal preparations have been reported in the media as being dangerous to

consumers or not meeting the claims that are being made about them. NZHT, like consumers and regulators, is concerned about these individual products and those that promote them.

44. These are, however, isolated incidents in an industry that supplies hundreds of different products. The policy and regulatory response for the whole industry should not be driven by a response to a small number of isolated incidents. NZHT believes that the history of the industry is generally acknowledged as being one of providing safe products. The cases cited are the exception rather than the rule. While the design of any policy and regulatory regime needs to take these examples into account the regulatory regime must also reflect the needs of the 95% of the industry that the Discussion Paper acknowledges to be low risk. An unnecessary level of regulation should not be imposed on the basis of a few isolated incidents. For this reason a comprehensive survey and analysis of the industry is needed to determine the whole picture of the industry rather than simply identifying those cases that are exceptional.

45. Other reasons for the critical nature of this information include as follows:

- It will accurately identify the range of products and operators in the industry, allowing an assessment to be made of the nature of the industry.

- Policy makers can accurately assess who will be affected by a new regulatory regime, the types of activity a new regime will need to cover, and determine the nature of the regulatory intervention that should be used for this industry.

- It will provide a basis on which to determine what the impact, in terms of cost on the industry and consumers, the regulatory regime will have.

Risk of Harm of Complementary Healthcare Products

46. The dietary supplements industry is very safe. Industry participants are ethical operators who are committed to providing safe high quality products. The reported deaths or serious adverse events from dietary supplements is very low. The Canadian Standing Committee on Health in its report *Natural Health Products: A New Vision* stated:

> Members also agreed that the NHPs [Natural Health Products] are different in nature from either food or pharmaceutical products. **We accepted the contention of the many witnesses who asserted that the vast majority of NHPs are inherently safe**…[Emphasis added]

47. The Discussion Paper itself acknowledges that 95% of CHPs would be "low risk" products. However, there does not appear to be any empirical evidence of what the actual performance of the industry under the current regulatory regime is, or what makes up the 5% that is considered to carry a risk of greater than "low risk". The nature of the risk that is being considered is vitally important to designing the regulatory response to that risk.

48. Again, this is another example of the information that could be collected as part of a systematic policy review of CHPs.

Compliance Costs of the Discussion Paper Proposal

49. Compliance costs are a very important consideration for the CHP industry. Small businesses make up 85% of the industry. Each business generally has a large range of relatively low volume products on its stock lists. Should the cost of listing each individual product prove to be excessive, it will result in an inability to continue trading as the impact on the bottom line may be too great to absorb or to pass on to consumers.

50. The concern about the impact of compliance costs is based on the current fees and charges applied in Australia. The cost of product licensing, site licensing, GMP audits of overseas suppliers and the annual renewal cycle applied by the Therapeutic Goods Agency ("**TGA**") in Australia if applied in New Zealand would be extremely expensive and time consuming.

51. Listing fees for each product are approximately $500. For a product range of 300 products, this equates to a cost of $150,000. In addition to this direct cost, each business will need to divert internal resources to meeting the listing requirements. In addition, based on the Australian experience, consultants may need to be engaged to assist in meeting the regulatory requirements. This could see the total listing cost per product including all these related costs amount to as much as $5,000. If all products in a company's portfolio attracted that level of cost, it could amount to a total regulatory cost of $1.5 million. Applying this scale of fees to the small businesses in the industry could very quickly make them unviable businesses.

52. The objective of a regulatory regime cannot be to force from the market businesses that currently have an unblemished record under existing regulation and which provide high quality safe products to consumers. Nevertheless, adoption of the Australian based system could very well have this effect.

Economic Growth Potential of the Complementary Healthcare Industry

53. The industry has the potential to make a significant contribution to the economic growth of New Zealand and to health outcomes for New Zealanders. The imposition of an unexpectedly excessive regulatory regime at high cost could undermine that potential. The potential exists for 85% of the industry comprising of small businesses to be forced out of the market. This would result in a curtailing of innovation, and limit the range of choices available to consumers. There will also be a significant regional economic impact with the closure of small businesses in diverse locations throughout New Zealand. Without a clear picture of the industry the costs and potential impact cannot be accurately evaluated.

54. By contrast there is an advantage for established large Australian and New Zealand CHP businesses from the introduction of such a regulatory regime. The void left by smaller New Zealand business leaving the market due to compliance cost concerns could be replaced by the high volume larger Australian and New Zealand businesses.

INFORMATION ABOUT INTERNATIONAL TRENDS

55. The Discussion Paper identifies that there is no formal international agreement on what constitutes best practice in the regulation of CHPs, although it does identify some trends emerging internationally. The comparative analysis table of other jurisdictions looks at the regulatory regimes in the United Kingdom, European Union, Canada and Australia. The analysis contained in this table is very basic and incomplete. It does not fully describe the actual arrangements in those jurisdictions. In addition, it does not indicate what work was carried out before they arrived at these regulatory solutions. For example, Canada undertook a very comprehensive review of its policy before arriving at changes to its regulatory regime.

56. The jurisdictions listed in the table are those that New Zealand policy makers traditionally use as guides when developing domestic policy and legislation. In the case of CHPs, however, a wider view must be taken. The countries listed in the table can be described as western nations, in which conventional medicine dominates the healthcare system and regulatory frameworks. In those countries CHPs are generally regarded as "alternative" products. There are many other jurisdictions that could provide valuable insights into the policy relating to CHP and the regulation of those products. In particular, jurisdictions which have integrated "alternative" treatments into their health systems might provide a better insight into how policy and regulation in New Zealand should develop. Those other jurisdictions include South Africa which has undertaken some recent amendments to its legislation. The European Union has also introduced recently a Food Supplement Directive relating to vitamin and mineral supplements, which is not referred to in the Discussion Paper analysis.

HARMONISATION NOT THE ONLY OPTION UNDER THE TRANS TASMAN MUTUAL RECOGNITION AGREEMENT

57. Harmonisation is not the only option available to New Zealand to address the special exemption status of therapeutic products. The others include "mutual recognition" and "permanent exemption". Harmonisation itself is not limited to the development of a single Trans Tasman regulatory regime and agency. Harmonisation can include using identical or similar standards in both countries or bringing regulatory requirements in both countries into closer alignment.

58. The potential benefits of the TTMRA that have been identified include lower costs to business, greater choice for consumers, and greater discipline on regulators contemplating new regulations. The proposal as currently framed runs contrary to these expected benefits at least for the New Zealand industry. This appears to be a symptom of New Zealand lacking a clearly defined and stated policy position which takes into account the overall national interest.

59. Only when the New Zealand policy position on the regulation of dietary supplements and complementary health products is resolved, can the most appropriate avenue to address the special exemption for CHPs can be assessed. Until such time as New Zealand is clear about what it wants to achieve in the CHP area, it is difficult to determine which approach best serves New Zealand's interests.

DEFICIENCIES WITH THE PROPOSED REGULATORY REGIME FOR COMPLEMENTARY HEALTHCARE PRODUCTS

60. While there is a fundamental flaw with the process being used to develop the regulatory regime for CHPs, which requires the removal of the proposal from the Discussion Document to allow due process to be followed, there are some significant issues about the proposal which we would like to bring to your attention.

61. The principal concern is that the model proposed for CHPs is based on the model adopted for the regulation of pharmaceutical products. **There is no indication that alternative models have been considered in the development of this proposal.** There are key differences that need to be taken into account when designing a regime for CHPs, as distinct from pharmaceutical products.

Food or Medicine?

62. The question that is often mentioned in determining how complementary healthcare products should be regulated is the products in question food or medicines. The answer to this question, in the minds of regulators, determines which regulatory approach should be taken towards complementary healthcare products. The Discussion Paper has come down on the side of regulating these products under the medicines regime. This is the current Australian approach, which provides for the regulation of complementary healthcare products under the Therapeutic Goods Act 1989.

63. This by no means is the only possible conclusion. Most papers on CHPs tend to agree that there is no one internationally consistent approach towards the regulation of complementary healthcare products. International approaches have in some papers been divided into two categories:

    (a) Two-category systems (for example Australia and the United Kingdom), regulating food and medicines, with complementary products regulated under the medicines regime or the food regime; and

    (b) Three-category systems (for example United States, New Zealand, and the proposed system in Canada), regulating foods, medicines and dietary supplements (or alternative term) separately.

64. With those countries that take a three-category approach, usually the third category sits under the umbrella of a two-category approach with the dietary supplements regime coming under either a food or medicine piece of legislation. It is interesting to note that the USA followed the New Zealand precedent of using a third category. The Canadian approach of as separate regime distinct from medicines and food goes one step further. Ultimately, the conclusion that can be drawn from the disparate approaches around the world is that CHPs occupy a middle ground in the food – medicine continuum.

65. The DSRs themselves, in the explanatory note, acknowledge the unique position of complementary healthcare products, stating that:

> These regulations, in a sense, fill the gap between the Food Regulations 1984 and the Medicines Regulations 1984, **in that dietary supplements are not "food" or "medicine" in the ordinary sense of those words**. However, they are "food" within the meaning of the Food Act 1981, and will be "related products" within the meaning of the Medicines Act 1981 if therapeutic claims are made for them.

66. The Regulatory Impact Analysis statement prepared by the Canadian Health Products Directorate on the regulation of National Health Products in its introductory paragraphs states:

> The regulatory regime for drugs (under the *Food and Drug Regulations*) is viewed as too rigorous for these products, given the long history of safe use that most of these products have enjoyed. At the same time regulation as food is not appropriate either.

67. The recognition that complementary healthcare products are not food or medicines is a very important distinction in determining the appropriate regulatory regime. The Discussion Paper proposal does not appear to reflect this distinction. The comprehensive work programme of the MACCAH, and a survey and analysis of the CHP industry as recommended by this submission should reveal the unique characteristics of CHPs, and allow an appropriate regulatory regime to be designed.

Complementary Healthcare Products are Not Pharmaceuticals

68. Taking the distinction from the section above further, complementary healthcare products are not pharmaceuticals. This is fundamental to the development of policy and regulation relating to CHPs. The proposal in the Discussion Paper appears to include CHPs in the pharmaceutical model.

69. Pharmaceuticals are produced by an industry that has many large multinational companies engaged in extensive research programmes. Generally the products are innovative novel chemical compounds developed through synthetic methods. The industry is based on investment in research and development, which involves extensive testing to determine if what has been produced is not toxic, can be safely taken by humans, and has the effect it was designed to achieve. The average cost of developing a new medicine of this sort is US$500 million, and it takes 10 – 15 years from discovery to market introduction.

70. The process of medicine development as a matter of course generates extensive data on the characteristics of the products in question before it has been introduced to market. This data can then be provided to regulators for assessment and review.

71. Another important distinction is that pharmaceutical companies are able to patent their discoveries and processes. The fact that patents are held provides a means by which those companies can recover the cost of development and any regulatory controls through the ability to exclusively market a product for a number of years.

72. This is not the case with CHPs. Individual producers do not hold patents over the ingredients in their products. The products in question are obtained from plant, animal or mineral sources and are generally found in nature. They are not innovative or novel. The healthcare benefit usually comes from the knowledge

surrounding the product that has been collected over many years of traditional use in particular cultures. There is no extensive developmental record of these products, and the people that manufacture the products do not have a monopoly on their manufacture and distribution. Their safety has been established by a history of safe use over many hundreds of years. In pharmaceutical parlance, they are generic products. The distinctive selling point comes from the reputation and quality systems of the person manufacturing the product.

73. The Discussion Paper makes much of the fact that the regulatory approach is risk-based. The regulatory intervention in other words is proportionate to the level of risk posed by the product. Three categories of risk are proposed:

- **Class I:** Low risk (most complementary medicines).
- **Class II:** Medium risk (over the counter medicines, some complementary medicines).
- **Class III:** High risk (prescription medicines, and other restricted medicines, which may include complementary medicines)

74. But the risk categories so defined are based on the model that is applied to pharmaceutical products. As discussed above the process of pharmaceutical development gives rise to specific data about a product, which through the operation of intellectual property law is owned by the developer of that product. The pharmaceutical developer is well placed to provide data and engage in a lengthy and expensive process to approve a product.

75. Such an approach is not appropriate for CHPs. There are a large number of producers and intellectual property rights are not held over the ingredients. Forcing a particular product into a box and requiring data similar to that for a pharmaceutical product in most cases would result in the manufacturers simply not bothering to pursue the matter further, because the cost of producing information equivalent to information provided by pharmaceutical companies would be prohibitively expensive. There is also no mechanism by which an individual company could recover that cost. Once the safety of a particular compound is established, others in the market place could simply free ride on that expenditure. This would deny access to what otherwise might be a safe product. There is also a lack of any documented assessment of the risk of CHPs, meaning that this proposal with respect to CHPs cannot fairly be described as risk based.

76. A further concern is that the developers of the proposal do not appear to have any particular expertise in CHPs. This was found to be the case in Canada, which has led to the establishment of a separate office to deal with CHPs. We understand that the Minister of Health has also acknowledged in response to a Parliamentary Question that there is a lack of appropriately qualified personnel in the Government.

77. The unique characteristics of CHPs and the industry that produces them must be clearly articulated before developing policy initiatives in this area. The way in which CHPs are developed is entirely different to pharmaceuticals. Given these

differences, the pharmaceutical model of pre-marketing approval should be applied to the CHPs industry.

Delegated Law Making Powers

78. We also have very serious concerns about the inappropriate structure proposed and the nature and extent of delegated law-making power. The Ministerial Council and Managing Director of the Joint Agency will be given the power to make wide ranging regulations which will be part of New Zealand law without the need for domestic adoption.

79. The wide ranging nature of the delegated law making powers mean that not only will detailed matters be prescribed, but matters of policy could also be prescribed which are more appropriately dealt with by the New Zealand Parliament.

80. Location and domination of the Joint Agency by Australia would compound this concern, in that the Australian perspective would shape policy relating to CHPs. Access to the decision-makers by New Zealanders would also be limited. The Discussion Paper does state that there will be offices in both Australia and New Zealand, but it appears likely that key decision-makers will be located in the Australian office making good consultation difficult to manage.

81. While access to Parliamentary review via the Regulation Review Committee and disallowance under the Regulations (Disallowance) Act 1989 is to be preserved, this does not address the fundamental issue that matters more appropriate for primary legislation are being determined by the Executive or officials.

82. This is heavy handed, involves intensive regulation and is lacking in transparency. It may be appropriate for high-risk products. It is quite inappropriate for low risk products like CHPs.

Unjustified Limitation of Judicial Review

83. Various specialist review processes are proposed, with a limited right to judicial review retained. However we are extremely concerned about the unnecessarily restrictive approach to judicial review. The Discussion Paper proposes that judicial review of the Agency's decision should be "limited to those who are directly adversely affected by the decision". In other words judicial review would be limited to an aggrieved applicant.

84. This is a significant limitation of judicial review in New Zealand. The comparison to Australian law is a false analysis. The Legislation Advisory Committee ("**LAC**") Guidelines state the principles applicable in New Zealand to the availability of judicial review.

85. The LAC states at paragraph 13.1.2 of the Guidelines:

> Because Parliament would not have intended to authorise unlawful action, **it is not appropriate for legislation to preclude or limit judicial review**. Section

> 27(2) of the New Zealand Bill of Rights Act confirms that such provisions should not be included in the most unusual cases. [Emphasis added]

86. The LAC concludes at paragraph 13.1.3 that:

> Except in the most unusual cases, legislation should not deprive people of the opportunity to seek judicial review of actions, nor limit their right to do so.

87. There is nothing exceptional or unusual about the Discussion Paper proposal that in any way justifies limiting of the right of people to seek judicial review of statutory powers exercised under the proposed regime. There is no analysis in the Discussion Paper on why such an extreme idea has been proposed. The danger of his proposal is that an illegal exercise of a power by the Agency could remain unchallenged for want of a plaintiff. For example, an unlawful decision in favour of an applicant would not be capable of challenge. It is not in the interest of the applicant to seek judicial review and any competitor in the market or concerned interest group would not be able to seek judicial review of the decision.

CONCLUSION

88. The process adopted to develop the proposals regarding CHPs in the Discussion Paper is fundamentally flawed. The timeline of initiatives in the CHP sector clearly demonstrates that the "cart has been put before the horse".

89. There is a lack of evidence to support the proposals in the Discussion Paper. In addition, the approach to complementary health in New Zealand is developing in a piece meal manner. The MACCAH has on its work programme the task of systematically collecting information about the complementary health sector and make recommendations to the Minister of Health. There is consequently a policy vacuum regarding CHPs. There has been no systematic analysis of the CHP sector from a New Zealand perspective.

90. The proposals in the Discussion Paper relating to CHPs should consequently not be advanced any further until such time as New Zealand's policy on CHPs and complementary health generally has been worked through the MACCAH process.

91. NZE would be happy to work co-operatively with officials to ensure that such a systematic analysis of the CHP sector takes place from a New Zealand perspective. But this discussion cannot proceed on the current basis that an Australian solution is the preferred option. We need a process which starts with a genuine open mind as to what is best for New Zealand.

MEDICAL DEVICES

92. The Discussion Paper also proposes a regulatory regime for medical devices in New Zealand. The Discussion Paper states that the proposed system is in line with international best practice and is based on the principles endorsed by the Global Harmonisation Task Force ("**GHTF**"). NZHT's concerns relate in particular to medical devices for use in the complementary healthcare sector.

Summary

93. NZHT's concerns about the proposals to introduce a new regulatory regime for medical devices relate to the delegated law making powers granted to the Agency and Ministerial Council. While the regime is based on GHTF principles, the critical aspect of the regime is the interpretation of the GHTF principles by the Agency in setting standards that medical devices must meet before being approved. Given the Australian domination of the Agency, there is a risk that standard promulgated by the Agency will be heavily based on Australian interests. Australian interests may not necessarily coincide with New Zealand interests and policy on these matters.

94. NZHT is also concerned to ensure that standards for complementary health devices reflect the nature and characteristics of those devices rather than being subjected to standards for devices usually found in western medicine. Related to this is the need to ensure that the standard setters and those that assess individual applications for complementary health devices have qualifications relating to the complementary health sector.

95. NZHT is also concerned about the uncertainty of the level of cost to industry of the proposed regime. NZHT's concerns relating to compliance costs for CHPs are equally applicable to the regulation of medical devices in the complementary health sector. The Discussion Paper does not contain any estimates of the costs that industry might have to bear. NZHT would like to emphasis that excessive costs could stifle innovation and research into devices to support the use of complementary healthcare options.

96. Finally, NZHT is concerned that a further discussion paper and consultation process on medical devices was commenced by letter dated 29 July 2002 from Medsafe to industry members. This is only days before the closing date for submissions on the Discussion Paper (2 August 2002). It seems that the proposed register is simply an interim step on the way to a new regulatory regime for medical devices in New Zealand. It is not clear from the face of the 29 July 2002 letter why this initiative is taking place before any decisions are made regarding the proposals in the Discussion Paper which people have been asked to make submissions on.

Interpretation of GHTF Principles

97. The Discussion Paper states that the proposed system is based on GHTF principles. This harmonisation project means that more and more jurisdictions around the world will be based on the same foundation. However, harmonisation does not mean that an identical approach will be taken around the

world. The interpretation of those principles by different countries varies taking into account various cultural, economic and historical factors. Consequently the promulgation of standards based on the GHTF principles is the critical aspect of the proposed regime.

98. **NZHT is concerned that standards promulgated at the Ministerial Council and Managing Director level under the proposed new regime, will be based on an interpretation of GHTF principles heavily influenced by Australian perspectives, given the location and domination of joint agency by Australian interests and personnel.**

Complementary Health Devices

99. There is currently an emerging industry developing medical devices for use in the complementary healthcare sector. Currently the classes of medical devices are listed on the basis of devices usually found in hospitals and doctor's surgeries. The Discussion Paper refers to medical device standards being developed by the Agency, to demonstrate that a device complied with the essential GHTF safety principles. The standards for complementary health devices should be developed to take into account the specific characteristics of the devices in question. The standards should not be excessive or unreasonable, by simply imposing rigid data requirements normally associated with devices used in the western medicine tradition.

100. Assessment of applications for complementary health devices should also only be carried out by personnel with appropriate qualifications in complementary healthcare to ensure a proper and fair assessment is conducted.

101. The earlier discussion in terms of the development of a New Zealand policy on CHPs and complementary health generally is also relevant in this instance. A clearly articulated policy position regarding the place of complementary medicine in New Zealand would assist the development of appropriate standards for the assessment of complementary health devices.

Recommendation

102. NZHT recommends that consideration be given to developing specific categories and standards for medical devices in the complementary health sector based on a systematic review identifying the characteristics and requirements of those devices.

APPENDIX I: OBJECTS OF THE NEW ZEALAND HEALTH TRUST

1. 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 complementary 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 bodies, 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.