

FURTHER SUBMISSION
TO THE HEALTH SELECT COMMITTEE

in response to the presentation by the Ministry of Health, Medsafe and Ministry of
Foreign Affairs and Trade

**AGREEMENT TO ESTABLISH A TRANS-TASMAN THERAPEUTIC
PRODUCTS REGULATOR**

28 April 2004

PRESENTED ON BEHALF OF
THE DIETARY SUPPLEMENTS CONSULTATIVE GROUP
including the following members:

- CHARTER OF NATURAL HEALTH PRACTITIONERS
- INTERNATIONAL NUTRITIONAL PRODUCTS ASSOCIATION
- DIRECT SELLING ASSOCIATION
- CITIZENS FOR HEALTH CHOICES
- NEW ZEALAND HEALTH TRUST

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EXECUTIVE SUMMARY

- a) The first submission lodged by the New Zealand Health Trust under cover of a letter of 6 April 2004 and including the briefing paper on the Treaty and its accompanying fact sheets, sets out the position of the Submitters in respect of the Treaty presently before the Committee.
- b) The Committee is required to report to the House on the Treaty as a whole and provide its opinion on whether or not the Treaty should be ratified. We are advised by the Ministry of Foreign Affairs and Trade that the Committee may also ask the House to debate its recommendations and call for a vote on the same if the Committee is minded to do so.
- c) This further submission is lodged by way of rebuttal of the claims made during previous Hearings of the Committee by representatives of the Ministry of Health, Medsafe and the Ministry of Foreign Affairs and Trade and their advisors.
- d) Throughout the presentation the officials made repeated reference to a lack of regulatory capabilities world wide as being a leading driver of the need for a single agency. Firstly, nowhere throughout the extensive debate and documents published on this issue have the officials provided any evidence whatsoever to substantiate this claim. Secondly, this supposed guiding principle is at variance with the national interest analysis produced which is clear that the driving reason for the joint agency approach is to satisfy Australia's trade requirements.
- e) The officials were clear in their presentation that mutual recognition between Australia and New Zealand is and has always been the preferred method of achieving our CER objectives and this is as reflected in the Trans-Tasman Mutual Recognition Act. The reason given here as to why mutual recognition has not been used is merely that mutual recognition would not be accepted by Australia given the current state of our regulation of dietary supplements. What this argument of course fails to deal with is the fact that all parties are in agreement that changes in the regulation of dietary supplements in New Zealand are required. The industry has never opposed sensible New Zealand based regulation and in fact would welcome the introduction of such a system. It is therefore non-sensical to discount the possibility of a mutual recognition agreement with Australia based only on the perceived inadequacy of the current system.
- f) Much was made by the officials of the principle of having "no lesser accountability" and the officials talked at length before the Committee about how they had worked to ensure that this was the case. With all respect it appears that the officials' view of what accountability would exist has been coloured by their intentions and their views of how the Treaty would in fact be implemented. The Treaty itself does not guarantee anywhere near the levels of accountability that the officials described before the Committee. Whatever the intentions or understanding of the officials as to how the implementation will occur, the Committee can of course only consider what the Treaty actually provides.

- g) The officials also made repeated reference to the ability for Australia and New Zealand to maintain national differences and whilst the Treaty does make provision for this, the criteria that are prescribed in the Treaty for justifying such differences are in fact so limiting as to make any real differentiation between the countries somewhat illusory. This is a case of the possibility of differences between Australia and New Zealand being more theoretical than realistic.
- h) Whilst the Treaty provides for a review process by which the decisions of the agency can be considered, the method of appointment of this merits review panel ensures that there will be no independent assessment or review of any such decisions. Although questioned on this point, the officials answers did not in anyway allay these concerns.
- i) While the officials continue to use the language of providing risk based regulation systems, they have continued to fail to supply any evidence for what would undisputedly be a markedly increased level of regulation, either from that which we currently have or from that which is proposed under any sort of sensible alternative New Zealand based regulation system.
- j) The officials continue to provide no assurances and the Treaty provides no guarantee of protection for the industries involved against cross-industry subsidization of liabilities. In the event of a significant pharmaceutical recall or liability there is no ability for the dietary supplements industry to protect itself against the inevitable cost recoveries that would follow.
- k) Based on the wording of the Treaty itself, the first submission of the New Zealand Health Trust and the lack of any tangible mitigation of industry concerns based on the presentation by the officials, the Treaty should not, in our opinion, be ratified. It is our submission that the House be asked to debate and vote on this Treaty to ensure that further time and tax payers funding is not spent proceeding down this track if it does not have the support of the House.

SUBSTANTIVE MATTERS

Lack of Regulatory Capacity

1. It does appear that the officials are now claiming that the lack of sufficient regulatory capability and resources worldwide is the driving force behind the creation of a single agency. This is at odds with the previously expressed driving forces which have included the requirement of trade with Australia and previously the public health and benefits of a consistency of approach.
2. The officials have now stated publicly what we have always indicated as being a likely consequence of the single agency, which is that it is seen as the forerunner to a globalised regulation of dietary supplements with likely no more than, to quote Ms Martindale, “three or four regulators worldwide”. The Treaty makes clear provision for the agency to have the power to join up with other international bodies. This is the clear intention of the agency and the officials behind it. This alone ensures that any limited control or accountability New Zealand would have under the single agency as proposed would be at best watered down and more likely completely destroyed when this new Trans-Tasman body later cedes its own control to a much larger international body.
3. Given that the officials have repeatedly relied on a claim of regulatory capacity it is surprising that no evidence has been produced to justify the same. In the absence of any such evidence being presented the Committee and the House should not look to instigate what is by the officials’ own admission a new piece of architecture in Trans-Tasman relationships and one which goes considerably further than any of its ancestors.

Mutual Recognition

4. Despite admitting that mutual recognition is established as the preferred method of ensuring open avenues of trade with Australia and pursuant to our CER obligations, officials appear to have dismissed mutual recognition as an alternative rather early in their consideration of these issues on the somewhat flimsy ground that the current state of our regulation of dietary supplements would not be adequate for Australia. This of course ignores the fact that the parties appear to agree that New Zealand needs to and will be undertaking a complete change in the way in which dietary supplements are regulated in New Zealand and there is no reason why this system cannot be developed in such a way as to ensure that Australian concerns are met. Alternative models developed to date show that all the Ministry’s stated public health objectives can be met by creating a simple New Zealand based regulation model based on the risk profile of the products involved and treating them as a third category separate from both medicines and foods. In answer to questions along this line, the officials responded that it would take too long by the time New Zealand developed such a system and then sought Australian acceptance of the same. In our submission, it is only due to the Ministry’s own failure to treat this as a viable alternative from the outset that it now finds itself in this position. Furthermore the mere fact of the delay in proceeding down an alternative route is not sufficient reason to adopt a patently less desirable alternative. It is clear that officials are using the argument that they are so far down the track of a joint regulator with Australia, that it would not be feasible

now to turn around and go down any other track. In response to this it is our submission that that sort of tactic can never be allowed to succeed because it amounts to circumventing due process and means that Government is instead presenting its proposals as a fait accompli.

5. On the issue of mutual recognition it was also interesting to note the officials' comments that proposed new joint agency would then look to develop mutual recognition Treaties with other countries. It is certainly interesting that Australia would accept mutual recognition agreements with other countries and yet purports to refuse to accept such an arrangement with New Zealand. Certainly if mutual recognition is seen as a good enough relationship for the joint agency to enter into with other countries, it is hard to perceive why it has been dismissed so flippantly in the present case.

Provision for National Differences

6. Article 11, clause 4 of the Treaty does appear to permit some regulatory distinctions to exist between New Zealand and Australia, however when the criteria that needs to be established to permit such a distinction are considered, it becomes clear that only in very rare cases will these criteria ever be satisfied. The Treaty requires that the differences between countries can only exist when particular public health, safety, environmental or cultural circumstances justify it. There is no entitlement for New Zealand to simply take a different view. Certainly these requirements could be used to enable for example, traditional Maori products to be exempt, however, given the fact that the physiology of humans is the same regardless of citizenship or ethnicity, it is difficult to envisage a circumstance in which public health or safety surrounding the taking of a particular product would be any different for Australians as opposed to New Zealanders. As far as the cultural exemptions or differences are permitted, whilst this clause could conceivably allow for traditional Aborigine or Maori remedies to be exempt from harmonization, questions then arise as to the treatment of other cultures within New Zealand. Are traditional Chinese, European, Pacific Island, Korean and so forth cultural remedies also to be exempted or are such cultural differences limited only to recognised indigenous cultures of a particular country? Given that for example, Chinese traditional remedies would be in use in both countries, once again it would seem that this would provide no basis for justifying a distinction between the countries and yet if cultural remedies are to be protected then other cultures than Maori or Aborigine cultures must be considered.
7. It does seem that if public health and safety is the key motivator for the regulatory system then any exemptions would have to be considered against this guiding criteria. If, for example, traditional Maori remedies did not have to be measured against the public health and safety criteria then the question would have to be asked of whether the decision was truly one of protecting the health of its constituents or merely a political decision.

"No Lesser Accountability"

8. Throughout their presentation the officials made constant reference to their benchmark of the joint agency providing no lesser accountability for New Zealand than a New Zealand based regulatory scheme and the officials were of the clear view that they have achieved this.
9. However a clear distinction has to be drawn between the representations made by the officials and the actual wording of the Treaty. In regards important matters like the application of the Official Information Act, the Ombudsman, the right for Judicial Review and the right of appeal from the Review Tribunal Decisions, the Treaty only states that the parties **may** legislate to provide for such matters. In legal terms the use of the word **may** is significant and it contrasts sharply with the use of the word **shall** in respect of other obligations contained within the Treaty. The word **may** clearly provides no obligation on either party to ensure that these matters are indeed provided for and notwithstanding any assurances the officials may have given to the Committee, the Treaty which the Committee is now asked to consider does not provide any absolute assurances in respect of any of these matters. This is incontrovertible. In our submission the use of the word **may** in these important regards is very significant and when contrasted against the deliberate use of the word **shall** in regard other obligations it is clearly not just an accident.
10. Against this background, the Committee and the House would have to act on the basis that the accountability provided by these important mechanisms is not guaranteed by the Treaty. And for this reason alone the Treaty cannot be regarded as providing no lesser accountability.
11. In any event the accountability that would exist, is in submission, window dressing only. While some requirement exists to consult with New Zealand, such consultation only occurs with the same New Zealand officials who have promoted the joint scheme from the outset. There is no ability for stakeholders to be consulted or to have any input or ability to force any review of change in any powers of the joint agency. Given the disregard that New Zealand officials have shown for the views of stakeholders throughout this process to date it is not surprising that the stakeholders can have no confidence that their protection rests solely in the hands of those officials who have brought the scheme in. A Treaty such as this cannot be accepted given that no accountability to the parties who actually fund the agency and are affected by it exists whatsoever.
12. Furthermore, any accountability contained within the Treaty ignores the political realities in existence between Australia and New Zealand whereby even if the New Zealand Government were to take a view in opposition to that of the Australian Government it is regarded as highly unlikely that a consensus would be able to be reached on the basis of the New Zealand position.
13. Furthermore, it is noted that while any change to the structure of the joint agency requires the consent of New Zealand, given that the agency is being set up such that the Managing Director has full powers the only realistic changes that could be made would be to limit such powers in which case it would be New Zealand having to obtain Australia's consent to any such limitation. As the Managing Director will have full power and authority significant damage can and is predicted to be done to New

Zealand interests without any change being required which would necessitate New Zealand consent.

14. The assertion of the officials therefore that the Treaty provides for no lesser accountability than would be the case for a New Zealand based regulatory system is therefore insupportable.

Merits Review Panel

15. Whilst the Treaty provides for a merits review panel to which stakeholders can apply to have the decisions of the agency reviewed, as the appointments to such panel are made by the same people as who appoint the agency staff, no real independent review is established. When questioned along these lines the officials stated that the merits review panel could consist of several hundred members, however once again there is no provision whatsoever for this in the Treaty and in any event in our opinion it is a question of the method of selection of such members rather than the number of them which is key. Given that there is no independent appointment process for such people guaranteed within the Treaty, the Treaty has to be considered from the view that the merits review panel will provide no objective assessment. Against this it must also be considered that the right to appeal further to the Courts of New Zealand is not guaranteed within the Treaty. Once again this is a provision that is only provided on the basis that the parties may legislate to include this. There is no absolute protection for New Zealand citizens in this regard.

Cross-Industry Subsidization

16. The proposed joint regulator is proposed to control the medicines, medical devices and dietary supplements industries. These are three distinct industries which should be protected against any requirements whether potential or real to subsidize another industry. In the event of a unwarranted recall or other event which brings either significant costs or liabilities upon the regulator, all industries which use that regulator will undoubtedly be exposed to the requirement to fund such expenditure. Once again, within the Treaty there is no protection for each industry against such cross - industry subsidization and no requirement that separate account and cost recovery records are kept in respect of the distinct industries. On this point it is interesting to note that the officials' own NZIER report indeed noted that while the proposal had an expected positive outcome for the pharmaceutical industry it was expected to be a negative affect for the dietary supplements industry, however, the overall affect was anticipated to be slightly positive. This is a very early statement indicating exactly the sort of cross-industry subsidization that is unwarranted and unfair and is likely to work to the detriment of the dietary supplement industry in particular.

Summary

- i. The Committee needs to ensure that its recommendations to the House are based on what is actually provided within the Treaty and not what the officials may indicated they intend to be the position.
- ii. To the extent that the Treaty is presented as being the result of certain needs, such claims must be discounted where there is an absence of real evidence supporting those needs. In the present case both the lack of international resources to staff such a regulator and the requirements of trading with Australia have both been given as reasons why the joint agency must proceed and yet no clear evidence that either is in fact the case has been presented. What is known is that mutual recognition, which is widely recognised as the preferred method of open trade with Australia, was discounted at the earliest stages and on very flimsy grounds.
- iii. The Treaty cannot be said to guarantee no lesser accountability to New Zealand. In important accountability regards the Treaty does not insure any such mechanisms will be in place but simply provides that such mechanisms could be contemplated. Once again no information or explanation is provided as to how in fact these mechanisms, if in fact provided for, would work and what the result is of two separate nations having separate, and therefore potentially different outcomes through any accountability process.
- iv. The Treaty remains light on important information such as how these accountability mechanisms would be put in place and be maintained along with details of the funding that would be required to establish and run this agency.
- v. The Treaty provides an assurance of maintaining national differences, however, this is not supported by the application of the criteria needed to allow such differences.
- vi. Based on the Treaty as it stands, it is our submission that the Treaty should not be ratified or in any way endorsed by the New Zealand House of Representatives and the House should be asked to debate the recommendations of the Committee and vote on the Treaty so that no further time and money is spent by the officials pursuing this course of action without the full support of the House.