

**ANALYSIS OF THE GOVERNMENT'S RESPONSE TO THE REPORT OF THE HEALTH
SELECT COMMITTEE ON THE THERAPEUTIC PRODUCTS TREATY WITH AUSTRALIA**
NEW ZEALAND HEALTH TRUST – SEPTEMBER 2004

INTRODUCTION

The Government response to the Health Select Committee's report continues the theme of all Government material released in this matter

That is to say the Government response:

- continues to assert highly controversial matters as fact without providing any evidence for them;
- fails once again to provide any justifiable basis for including complementary health care products within the same regime as that controlling pharmaceutical products;
- bluntly asserts that the new agency would be no less accountable to New Zealanders than a stand alone New Zealand agency when this is patently incorrect; and
- sets out a number of untruths and half truths deliberately designed to lull the industry, consumers and Members of the House into supporting its proposal.

In addition this Government response makes it clear that the Government has no intention of following the specific requirements of the Health Select Committee in a number of important regards because, as the New Zealand Health Trust has repeatedly said, the Government cannot meet the requirements of both Health Select Committee reports whilst still implementing the terms of its deal with Australia as set out in the Treaty signed in December of last year.

This paper will consider the Government response under the following headings:

- Scope of the proposed agency
- Accountability
- Justification
- Misleading statements contained in the Government response
- Areas where the Government has indicated that it has no intention of following the Select Committee recommendations.

1. Scope of the proposed agency

- 1.1 The Treaty signed with Australia and the Government response continue to make it clear that the Government intends to press ahead with regulating complimentary health care products as part of the wider category of therapeutic products which will also include pharmaceuticals and medical devices. This is contrary to the clear recommendations of the Health Select Committee in both of its reports in this regard.
- 1.2 The Government response sets out that its intention is, as the industry has always predicted, to merely have a separate division within the new agency which is charged with running each of the three distinct industries (being pharmaceutical, medical devices and complimentary health products). What is equally clear is that they will all be under the control of the same managing director, the same global cost recovery systems, the same over bearing bureaucracy and culture of fear and established primarily under the pharmaceutical framework. It is this decision that goes to the heart of the industry concerns and the industry **unanimously opposes** the inclusion of complimentary health products as part of the broader category of medicines. As the first Health Select Committee report quite correctly set out, they are their own category distinct from both medicines and food.
- 1.3 Not only does this go to the heart of all objections to the proposal, it is the fundamental reason why the Treaty signed by the Minister of Health in December last year cannot be made to reconcile the concerns of industry, the best interests of the New Zealand public or the clear recommendations of each of the two Health Select Committee reports.
- 1.4 The Government response acknowledges at the top of page 4 that the Agency they propose is **an entirely new form of regulator and differs from any existing New Zealand body**. Given this the proposal becomes far more than simply a health issue and becomes an issue of the extent to which, if any, the New Zealand and Australian Governments should merge functions. The New Zealand Health Trust submits that this is a serious constitutional issue which requires far broader debate than the Government has seen fit to instigate and should be considered by a much wider group of officials than simply those in the Ministry of Health. Specifically public submission and debate should be sought on the issue of having joint regulatory bodies between the two countries.

- 1.5 The agency proposed is **not a natural extension of CER**. The Governments of Australia and New Zealand recorded under the Trans-Tasman Mutual Recognition Act that CER was to be carried out through a process of mutual recognition which the Minister of Health now wishes to abandon in favour of full harmonization on the basis of New Zealand adopting the Australian model. To promote this Agency as a mechanism to achieve our CER objectives is quite false and misleading.
- 1.6 The response quotes the lack of pre market approval under the current regime as a reason supporting the joint agency. Firstly, there is no reason that pre-market approval could not be instigated under a New Zealand system of regulating medical devices if required and secondly it must be noted that extensive pre-market approval requirements in Australia still failed to prevent the Pan Pharmaceuticals debacle.
- 1.7 It is of interest to note that the very example the Government has given, that of heart valves, is one in which the Australian Therapeutic Goods Administration (TGA) has been strongly criticized for the lack of public safety achieved by its pre-market approval systems. A recent programme broadcast on the ABC's Radio Australia highlighted just how the TGA operates, demonstrating that its extensive rules served only to protect the manufacturers of medical devices and the bureaucracy itself and did little for public safety. For a copy of the transcript of this programme see <http://www.abc.net.au/rn/talks/8.30/helthrpt/stories/s1191667.htm>.

2. Accountability

- 2.1 Despite the often repeated claim by the Government that this Body will be no less accountable than any New Zealand equivalent, this simply is not true in any practical sense. There cannot be equivalent control or accountability where a Body responds to two masters equally. The mechanisms may be there on the face of it but the practical implications of each country utilizing them in their own way remain. Operation by consensus by its very nature means that **New Zealand can do nothing without Australia's agreement**.
- 2.2 The Government response makes much of the fact that New Zealand constitutional processes (such as Select Committees, Regulation Review Committees, Ombudsman, Official Information Act, not to mention a review by our Courts and Parliament) will all remain in place and will be able to consider and review the

actions of the Agency. What the report of course fails to say, is that none of these Bodies will have any power to make any change to the system of regulation as a result. All accountability mechanisms therefore are quite toothless and differ significantly from the current system whereby if a serious deficiency or unfairness is shown our Parliament has the unfettered and total ability to change the same at will. Under the joint agency proposed, **New Zealand has no power whatsoever to make any change to the system once established.** Any change sought by New Zealand would require Australia to agree which in itself is the ultimate fetter on all accountability mechanisms and certainly one which currently does not exist anywhere else.

- 2.3 The report sets out in the last paragraph of page 2 that the proposed joint therapeutics product regulatory agency would “retain New Zealand control over ... the decision making process.” This is patently untrue. Control is passed completely and for practical purposes irrevocably to the agency and once passed New Zealand would not be able to control anything on its own initiative. It can make representations and arguments and the like but has no absolute power. This is clearly a fetter on the New Zealand Parliament. Even New Zealand’s ability to exit from the Agency is severely hampered under the terms of the Treaty requiring not only a three year period from the date the decision is made until the time of exit is allowed, but it is also clear that significant hardships, both political and financial would result.

3. Justification for the Agency

- 3.1 Once again the Government claims that New Zealand does not have the expertise to “go it alone”. As has been a continuing theme with Government papers on this subject, no evidence is provided for this, nor is any distinction made between the three industries the Agency is proposed to regulate. Is the Government suggesting that there is a lack of pharmaceutical expertise, medical device expertise, and/or complimentary health care product expertise? For its part the New Zealand Health Trust is only interested in the regulation of complimentary health care products and certainly disputes that the claim of lack of expertise can be borne out in this field. It goes without saying that New Zealand can have access to information and research from all around the world and does not have to re-invent the wheel in every instance here and that any stand alone regulator here in New Zealand could access and use such information in the same way that any other country could. It does seem to go

entirely in the face of the Government reasoning used when the right to appeal to the Privy Council was abolished to say that New Zealand is not adequately resourced to provide for itself.

- 3.2 The Government response claims that the Joint Agency would provide a lower cost to New Zealand businesses however, in respect of complimentary medicines this is entirely at odds with the New Zealand Institute of Economic Research Report that the Government tabled at the first round of Select Committee Hearings which indicated that the cost to New Zealand complimentary health care businesses would **increase** under this proposal.
- 3.3 On page 7 of the Government response three supposed benefits of the proposed joint Agency are listed, however each of these three would be obtainable under a sensible New Zealand system of regulation which has always had the support of the New Zealand industry. To site these as reasons in support of a Joint Agency as opposed to a review of the New Zealand laws in this regard is misleading.

4. Misleading Statements

- 4.1 The Government response states that “going it alone is not a viable option” however it fails to provide any evidence for this nor does it properly distinguish between the three classes of products to be regulated and in particular complimentary health care products which the Select Committee made quite clear should be classed as a separate category. Government Officials at Select Committee hearings themselves acknowledged that they never properly explored the option of overhauling the New Zealand regulatory system for complimentary health care products and then turn to consider mutual recognition, but rather they discarded mutual recognition as an option based solely on the claim that Australia would not accept our current system. There has never been any disagreement from industry or consumer groups alike that the regulation of complimentary health care products in New Zealand is due for review.
- 4.2 The Government response claims that the Treaty and the proposed Agency would preserve New Zealand’s influence over the regulation of therapeutic products and retain New Zealand’s controls over such decisions. This cannot be true when New Zealand loses the ability to make any decision it sees fit in the interests of its citizens as of right and without fetter. Regardless of what accountability and scrutiny

mechanisms may be put in place the fact will remain that New Zealand will not have the ability to make any changes it likes unless it can obtain Australian agreement to those changes.

- 4.3 The Government response claims that the cost to New Zealand businesses under the joint Agency will be lower however, the New Zealand Institute of Economic Research's report indicates that the cost will increase for complimentary health care products and many businesses are predicted to shut down entirely or relocate to Australia should this Agency proceed.
- 4.4 The Government response points out that all decisions of the Joint Agency would be subject to a merits review process but fails to point out that the merits review panel would be appointed by the same people who appoint the key staff of the Agency thereby insuring that there is no true independent review at this stage.
- 4.5 The Government response claims "the proposed joint therapeutics agency would be accountable to Parliament in much the same way that Crown entities are accountable to Parliament". Once again this is patently untrue because Parliament in the case of New Zealand Crown Entities has the absolute ability to make any changes to the law that may be required as a result of its scrutiny. Under the proposed agency the New Zealand Parliament would not have the power of its own initiative. Similarly the New Zealand Parliament's reviews, Select Committee enquiries and briefings will serve no other purpose but to highlight areas of difficulty. As already stated the New Zealand Parliament will not have any ability to do anything as of right.
- 4.6 The Government response claims on page 9 that the Treaty "authorizes sub delegation of some, mainly administrative powers". This is a gross mis-statement of the position under the Treaty which enables the managing director to delegate some or all of his powers as of right. There is no limit to these being administrative powers and the Government response totally fails to deal with the magnitude of this issue. Whilst the Ministerial Council must consent to the appointment of the managing director there is no similar power for the Ministerial Council to approve any sub delegation.
- 4.7 The Government response, in discussing the reasoning for not providing for no time limit for disallowance of rules claims that not having a time limit will place an incentive on officials to ensure that the rules in order do comply with the delegated legislation

and to ensure that scrutiny is conducted quickly and effectively. There is no logical connection between having no time limit and these supposed incentives. The only impact of having no time limit would be disadvantage stakeholders who may lose their ability to challenge the rule based on this technicality.

5. Areas where the Government has indicated that it has no intention of following the Select Committee recommendations

5.1 By its response Government has made it clear that it has no intention and indeed no ability to adopt the following recommendations of the Health Select Committee:

- Complimentary health care products would not be regulated as a separate category distinct from both medicines and food;
- There will be time lines in place for the consideration and disallowance of regulations and rules;
- Partial disallowance of rules will not be permitted;
- In a number of other important matters the Government response simply says that they are in the process of drafting legislation and will take Health Select Committee recommendations into account without providing any further detail.

6. Conclusion

6.1 The Government response claims that the proposed Agency will achieve greater consistency between the New Zealand and Australian Parliaments in the regulation of these products. What it fails to go on to say however is that this consistency is, in every case, achieved by New Zealand giving up its own systems and adopting carte blanche those in use in Australia. This is not a joint approach but New Zealand adopting the Australian approach without question and without any evidence of Australian willingness to make changes to their own system to more closely mirror ours.

6.2 This system cannot be said in any way to have the same accountability as a New Zealand based Agency, as the New Zealand Parliament will not have the ability to make any changes it sees fit unless it can obtain the consent of the Australian Government. In this way it is a clear fetter on New Zealand's ability to make its own decisions.

- 6.3 Finally, it is reinforced even further from the Government response that the Treaty signed by the Minister of Health in December last year cannot be reconciled with the clear, concise and logical recommendations of the Health Select Committee in its two reports.

Presented by the New Zealand Health Trust
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