

TREATY TO ESTABLISH A TRANS TASMAN THERAPEUTIC PRODUCTS REGULATOR

BRIEFING PAPER

Prepared by the New Zealand Health Trust
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OVERVIEW:

This paper addresses the Treaty to Establish a Trans Tasman Therapeutic Products Regulator signed between the Australian and New Zealand Governments on 10 December last year and the accompanying fact sheets from the project website (www.jtaproject.com). These documents are attached to the printed version of this paper.

The Treaty and accompanying fact sheets at first glance present a picture of a regulatory system with the necessary accountability which allows for national differences. The reality however is quite different. As soon as one scratches the surface, it is clear that the regime Government has signed New Zealand up to will be completely unsatisfactory. This paper outlines why.

In the explanatory information, no evidence of necessity or rationale for the system is provided, highly contentious issues matters of opinion are expressed as fact and the façade of accountability and proper national sovereignty simply will not hold up under real-life conditions

Furthermore, important matters which go to the heart of the system are to be decided subsequently. This of course means that if the Scheme was approved, these outstanding matters could seriously affect the viability of New Zealand businesses and undermine our national sovereignty.

It is clear that considerable effort has been spent on dressing the treaty up to be as palatable as possible in the face of strong opposition. However to be fooled by such window dressing would be to ignore the realities of the proposal which have not substantially altered from that which was unanimously rejected by the Health Select Committee in its December 2003 report.

SUMMARY

- The treaty ignores the central principals of the Select Committee Report.
- It contravenes natural justice and is quite inappropriate to have two industries which are markedly different in their philosophical standpoints, risk levels and ingredient bases and which are in effective competition, regulated by the same body which is to be dominated by players from one of those two industries.
- The treaty provides far too much power and discretion to the Managing Director and enables all such powers to be passed to other persons or entities who may not have been approved by the New Zealand Minister.
- The ability to retain national differences is so narrowly drafted to ensure that it would be of little effect.
- NZ influence on the Board must be measured against the fact that the most powerful player, the Managing Director, does not report to the Board.

- Many vital details are still missing, i.e. the amount New Zealand would contribute initially, the initial rules, the make up of review boards, and so forth.
- The proposals indicate significantly increased compliance costs for New Zealand businesses.

SPECIFIC COMMENTS ON ACCOMPANYING FACT SHEETS

1. Natural Health Products are from the outset and without any discussion or justification deemed to be a type of medicine. This is a strong contested matter and is out of line with significant international precedent which recognises the necessity for regulation of Natural Health Products as a separate category distinct from both medicines and foods. At the select Committee hearings even the TGA's own expert Dr Keller, noted that the EU do not treat the majority of mineral and vitamin supplements as part of the medicine based framework he described.
2. The proposal sets FIVE different stages of regulation that must be complied with, without counting any of the review or appeal stages that may be involved. Regulation applies to the importer of materials, the manufacturer, the sponsor (supplier), the retailer and to the exporter of the end product. Inevitably the total compliance cost over five stages of regulation would result in significant increase to the eventual cost to the consumer.
3. The proposal records that regulation to this extent is not currently in place but uses that alone as justification for the same. At no stage is the more important question asked of whether a five-staged intensive system of regulation is necessary? The mere fact that something is not there now is not evidence that it is needed. This is but one example of the defective logic used in the fact sheets.
4. Objectors to the proposal have been repeatedly assured through the Ministry Discussion Paper and Select Committee processes that the proposal was not an extension of the TGA but a new system being developed. Despite many requests, specifics of how the system would differ were not forthcoming and still in this late stage there is no clear statement given to show how this is anything other than the TGA extending its authority and control to New Zealand. Obviously the legal entity and its name would change but beyond that the question remains of what the differences would be from the body that permitted the Pan debacle despite its extensive bureaucracy, and which is widely disliked in its own jurisdiction. Is it likely for example that a new body would see a change in any of the key decision making personnel? No comment is made on this - leading to the likely conclusion that there would be no real change.
5. The fact sheets make the claim that different regulations would be permitted in each of the two countries to satisfy local differences, however the wording of the criteria required means it is highly unlikely that this would ever be used

other than as a means of providing specific rules for traditional Maori products.

6. The fact sheets provide that harmonisation is the preferred alternative to the two countries working together. This is quite inconsistent with the Select Committee report that recommended Mutual Recognition instead of harmonisation. Further the Fact Sheets claim that harmonisation is consistent with the “broad objectives” of the Trans Tasman Mutual Recognition Act. This is incorrect. That Act explicitly recommends development of Mutual Recognition agreements between the two countries - to use it as justification for the abdication of rights proposed here is to pervert the spirit and intent of the legislation.
7. Fact Sheet 2 sets out a number of what it describes as ‘reasons in support of the Joint Scheme’. Upon consideration however the reasons given do not particularly support a Joint Scheme – all of the requirements described can be achieved through proper New Zealand based regulation. Once again this shows that the justifications being given simply do not support adoption of the Joint Scheme despite Government claims to the contrary.
8. The fact sheets present as fact what are in reality no more than matters of opinion and then use these claims to justify the Joint Scheme. For example the fact sheets claim New Zealand does not have the resources to regulate this industry. This is strongly disputed and not supported by any evidence and yet is presented in the fact sheets as a reason justifying the Joint Scheme.
9. The fact sheets refer to there being no global consistency of approach to the regulation of Natural Health Products. However once again this does not of itself mean there should be. Whilst each country is self governing, the lack of international harmonisation is not necessarily something to be corrected and this should not be presented as a justification for the Joint Scheme without significant nationwide constitutional debate.
10. The fact sheets provide that most Natural Health Products, as so called lower risk products, would have lighter controls than pharmaceuticals. However this is not the same as ensuring the controls will not be excessive. It just says that they would be somewhat less rigorous than for drugs. Under the proposed regime, in all likelihood the controls would be out of all justifiable proportion to the actual risk profile of the products.
11. The fact sheets fail to mention or deal at all with the actual risk levels of Natural Health Products except to say that those that are seen (at regulators discretion) as lower risk would have lighter control. The fact that this sort of onerous five-stage bureaucracy isn’t already in place is because it has never yet proven justified given the low level of risk inherent in these products.
12. Further it is of concern that the risk assessments would be at the whim of the agency which would without doubt be predominantly staffed by those who are pharmaceutically trained and therefore assessing Natural Health Products with an inappropriate methodology.

13. The proposals as amended now refer to ‘low-risk’ products (without any assurances as to which Natural Health Products may qualify for this tag) being self certified on the internet rather than having to be evaluated by the agency. Whilst we are pleased that they are now seeing the wisdom of the approach we have been trying to instigate, the obvious conclusion is that if we are using a self certified system for Natural Health Products, without individual assessment, then why do we need the Joint Scheme? This could just as easily be done in New Zealand. Given this proposal how can the proponents claim the need is based on a lack of resources in New Zealand?
14. The fact that individual formulations created by practitioners for patients are exempted clearly demonstrates that public safety is not the Government’s principal concern.. If it were, then why should the safety of these consumers not be as protected as the consumers who buy mass produced Natural Health Products.
15. The central platform of the proposal is a pre-approval requirement for all “advertising” which is defined extremely widely to cover almost any discussion of products in any form. This is pure income generation and is unjustified. In every other instance of industry or general control of what advertising may contain, the system involves a set standard and those who do not comply are prosecuted. Why should this industry instead require every ad to be pre-vetted at enormous and unnecessary regulatory and compliance cost?
16. Although the fact sheets promise consultation in both countries for the making of rules (regulations) and provides that these would be subject to possible disallowance in each country. However although theoretically possible, once the Joint Scheme is in place it would be practically (and politically) virtually impossible to go against Australia. The views of New Zealanders would have to be weighed against the wishes of our major trading partner and the little influence the public can have over our regulations is likely to be significantly reduced as a result.
17. The fact sheets record once and for all that the Joint Scheme would be an Australian entity.
18. The detail of the operation of the scheme, which will determine the true extent of the impact this would have on businesses and consumers in New Zealand, is likely to be unknown when the treaty is presented to the House for ratification. To pass the enabling legislation without knowing these details is tantamount to signing a contract without reading it.
19. The fact sheets detail that significant appointments such as the Managing Director of the agency have to be by consensus between the two Ministers. Given however the desire of the Minister to do everything the TGA has wanted so far, how can we have any confidence that anything would change?
20. The Managing Director is classed as a statutory decision maker but not a public servant. This raises serious questions of accountability - who he or she would serve if not the public?

21. It cannot be overlooked that even in a scenario where New Zealand and Australia have an equal say in decisions, they do not, and will never have, equal bargaining positions given the importance of Australia to our economy. The reality remains that we can be politically 'strong armed' as needed.
22. It is an inescapable conclusion that any accountability to New Zealand is in fact illusory because of the political pressures and differences in relative strengths.
23. Whilst provision is made for proper books of account to be kept for the agency there is no requirement for the accounts to differentiate between pharmaceutical products and Natural Health Products. This means that the Natural Health industry cannot protect against subsidisation of another industry with which effectively competes against.
24. The fact sheets provide that consultation is to be undertaken on how the Joint Scheme would fit in with important protection mechanisms like the Ombudsman and the Official Information Act. Once again it is inappropriate to ask that Parliament pass the enabling legislation before important details are worked through.
25. Whilst New Zealand is given a power to disallow regulations made by the Joint Scheme, even if the political difficulty in doing so could be overcome, there is a significant restriction on the power of our Parliament in that regulations may not be amended or disallowed in part. Faced with having to throw out the whole set of regulations over what may be small areas of concern, even more pressure would be on New Zealand to approve the regulations as tabled, objections notwithstanding.
26. There is specific reference to the fact that even if Select Committee were to recommend against any proposed regulations, these recommendations can be ignored.
27. Whilst there is provision for merit review panels and expert advisory panels, the ability of such bodies to act as effective 'checks and balances' on the Joint Scheme must be measured against the fact that they are to be appointed by the Ministers and would therefore be bound to be 'stacked' with supporters of the Joint Scheme. These bodies are therefore likely to be of limited use.
28. It is clear that proceeding with the establishment of the Joint Scheme prior to parliamentary approval is an attempt to apply economic pressure. No doubt the Minister will argue in the house that to vote against the treaty would waste considerable taxpayers money because work would then have to start again.

SPECIFIC COMMENTS ON TREATY

29. The treaty is made between the Government of New Zealand and the Government of Australia. No reference is made to the separate State Governments in Australia and no details given as to whether or how the individual States are required to ratify and adopt the system proposed. We know that to date the TGA has not had the full support of all States and accordingly this is very much an issue.
30. The definition of therapeutic products in the treaty is so wide as to cause considerable concern. Anything that is taken, or is likely to be taken, for a therapeutic effect falls within the definition. Under this description the treaty obligations would apply to a far wider class than is commonly anticipated. For example vegetables, fish, water and even oxygen could be arguably fall within the definition.
31. It places too much unnecessary power in the hands of the agency to be the sole determiner of which products are to be exempted from the regime. No regulatory system can operate without appropriate definitions to ensure consistency of application.
32. The treaty provides that the Government shall ensure that the enabling legislation is enacted. Although this is not the place to consider the issue, the question does arise of what the implications are if this minority Government cannot carry out the obligations it has agreed to.
33. The treaty makes clear reference in Article 3, cl 10 and Article 19, to the future plans to extend this regime to other parties thereby further diluting any New Zealand influence.
34. Whilst some details is gone into to describe the makeup and supposed impartiality of the Board (Article 6), Article 7, cl.3 makes it clear that the Managing Director does not report to the Board. Therefore any New Zealand influence on the Board is of no relevance to the extensive statutory decision making powers of the Managing Director.
35. The requirement in Article 8, cl.1(c) that there be no “unnecessary duplication” of accountability requirements is a clear attempt to limit accountability that would otherwise be required. Who determines what is “unnecessary”? Clearly the regulator and those supporting it will argue that separating accountability is unnecessary, however the stakeholders are likely to take a different view.
36. By Article 9, cl.1 it is clear that the Minister cannot control the regulatory powers of the Managing Director and the Managing Director can delegate and allow sub-delegation of those powers. So even if New Zealand approves the appointed Managing Director, all powers could then be delegated to someone of whom we do not approve and there would be no redress.

37. Article 11, cl.4 appears to permit some regulatory distinctions to exist between the two countries and no doubt the proponents of the Joint Scheme will try and make much of this. The wording however means that differences can only exist where particular public health, safety, environmental or cultural circumstances justify it. There is no option for us simply to take a different view. It is difficult to imagine in fact how these requirements could ever be invoked other than to protect traditional Maori products and this exemption again casts doubt on the claim that public safety is the key motivation for the Scheme.
38. Article 13, cl.10 provides only that parties may legislate to provide for appeal rights from Review Tribunal decisions and Article 14, cl 1 does the same in respect of judicial review. There is no compulsion to do so.
39. Given the manner of appointment of the Review Tribunal members, it is onerous to require business to absorb the cost of three hearings in order to have the matter independently assessed. There is the initial application, the Review Tribunal merits review and then the appeal, if those rights are given. That is an extremely expensive process for businesses to incur in the event of an unfair or unwarranted use of the extensive discretions of the Joint Scheme.
40. Articles 16, 17 and 18 enable either government to seek consultation, review or amendment. No similar powers are vested on the parties affected by the agency and recent events suggest that political pressure from Australia is likely to have more influence with our Minister than any lobbying from local industry.
41. By Article 15, cl.1 New Zealand is required to fund and provide assets to the Australian body. No details of this funding has been given.
42. Under Article 20, cl.3 it takes 3 years to get out once we commit ourselves to this regime and if the Joint Scheme is wound up New Zealand loses all interest in the assets of the agency, even though we helped to fund its set up.

RECOMMENDATIONS

- The Treaty should not be ratified
- Natural Health Products must be classed as a separate third category separate from both medicines and foods and regulated accordingly by a specific stand alone regulatory body and based on the risks and issues specific to these products.
- Appropriate New Zealand regulation be instigated using the existing negative list approach for product ingredients rather than the “white list” approach sought by the TGA.
- Advertisements not be subjected to a pre-vetting system
- The proponents should be required to provide full copies of all initial rules (regulations) and fees, with assurances of no changes for a minimum period, before the enabling legislation is even considered so that the full impact of the scheme is clear.