

COMPLEMENTARY HEALTH BRIEFING PAPER

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NATURAL HEALTH IN NEW ZEALAND

- Natural health products are regularly used by 62% of New Zealanders
- Estimated industry turnover \$300 million per annum
- Industry characterized by a very high proportion of SME's
- 85% of businesses employing less than 10 people
- Average business currently stocking 300-500 product lines
- Inherently low risk products with acknowledged excellent safety record
- Huge growth and innovation potential e.g. colostrum and lactoferrin products, and an increasing world market for natural products.
- An appropriate regulatory system would enable a significantly enhanced export market under a NZ specific brand.

THERAPEUTIC PRODUCTS AND MEDICINES BILL

- During 2003 the Health Select Committee *unanimously* concluded that the best option for NZ complementary health products was strengthened domestic regulation specific to the industry (i.e. not a pharmaceutical model of regulation)
- Despite this report, in December 2003, Labour signed the Agreement with Australia irrevocably committing themselves to this proposal. The period of so-called 'consultation' followed the signing of this Agreement.
- This Bill would give effect to that 2003 Agreement *without alteration*. Claims by NZ First that the Bill has changed significantly from the earlier Agreement cannot be substantiated.
- The Bill establishes the proposed agency and cedes control of complementary health products, medical devices and pharmaceutical medicines to it.
- Fees, charges, permitted products, approval systems etc are not contained in the Bill but would be later determined by regulations (called "rules and orders") to be made by the proposed agency.
- No independent risk assessment has been provided nor has the Government given any proper justification that necessitates the use of a pharmaceutical regulatory model as opposed to an industry specific model (distinct from both medicine and food).
- Under the Bill the regulation disallowance system is toothless, penalties are overly onerous and such appeal rights as exist are virtually worthless.

THE PROPOSED AGENCY (ANZTPA)

- Is an extension of the existing and unsuccessful Australian TGA system (strongly criticized by the Australian National Audit Office) to both countries.
- Headed by Ministerial Council of the health ministers of Australia and NZ. NZ will be unable to make any changes without Australian consent
- NZ has one guaranteed appointee to the five member Board that notably controls finance and administrative matters only.
- The agency managing director holds the key powers and would make the decisions that determine the full impact on business and consumers.
- The inclusion of other countries into the scheme is anticipated without detail as to how that would dilute New Zealand's voice.
- Not specifically required to have regard to Treaty of Waitangi obligations
- Adopts Australian privacy, interpretation, disallowance and penalty frameworks, but contains no adoption by Australia of any existing NZ frameworks.

IMPACT ON NEW ZEALAND

- The agency would impose a level of bureaucracy which is unprecedented and unwarranted for complementary health products.
- Compliance costs will increase drastically with no corresponding public benefit.
- Significant numbers of products will no longer be available, partly through unnecessarily restrictive rules but predominantly through safe and useful products ceasing to be economically viable.
- The majority of domestic SME businesses in the complementary sector are predicted to close or relocate overseas. The cost burden would disproportionately affect small businesses while assisting large corporations.
- The downstream effects would be reduced consumer choice and increased cost of the products that remain, a virtual halt on innovation and a crippling of the emergent export market for NZ natural health products.
- The proposed short term license fee rebate would not significantly reduce the impact on NZ businesses as these costs are the smallest part of the total compliance burden of such a system on business.

WHO IS SUPPORTING THIS BILL & WHY

- The Government has irrevocably committed themselves publicly and politically to this proposal and now is forced to try and bluff their way through despite the groundswell of opposition to it from the NZ public and industry.
- False claims are being made that 80% of NZ industry support the proposal. One Australian company in fact now owns both Nutralife and Healtheries that between them do have significant market share. They are known to support this proposal. Those companies are already TGA approved and stand to benefit considerably from the loss of domestic competition this proposal would bring about.
- An early Australian regulatory impact statement noted that this proposal would give an immediate commercial advantage to Australian businesses. This can be extended to include giving a commercial advantage in NZ to the few large NZ companies currently already TGA approved.
- Claims by a group calling themselves “Natural Products New Zealand” that they represent the views of the natural health industry in NZ are demonstrably false.

OUR POSITION

- Good quality regulation of complementary products is required to ensure product safety, that only properly evidenced claims are made and high quality manufacturing. The Australian TGA system however is not the only or the best way to achieve this.
- While closer ties with Australia are inevitable, ANZTPA is not a desirable system to adopt and would impose excessive compliance costs on local businesses that provide low risk products with no appreciable public safety benefit.
- Regulation must be proportionate to risk. Complementary health products should not be regulated under a pharmaceutical regulator but under a purpose designed industry specific regulator that properly protects consumers while stimulating innovation and business growth potential.
- The key components of the recommended regulatory model are set out in the December 2003 report of the Health Committee. Detailed regulatory proposal work has also been provided by Johansson Consulting (Australia) and the NZ Health Trust.
- This issue provides an excellent political opportunity with widespread public opposition to the proposal and Labour having painted themselves into a corner.

For more information please see the full New Zealand Health Trust submission to the Government Administration Committee (attached).