NZ Health Trust
Protecting your Future

A Summary of Concerns

WHY SHOULD I OPPOSE THE AUSTRALIA NEW ZEALAND THERAPEUTIC PRODUCTS AUTHORITY (ANZTPA) *AND* THE THERAPEUTIC PRODUCT & MEDICINES BILL?

INTRODUCTION

While there are many issues involved, the opposition to the Government proposals to hand control of all therapeutic products to a single Trans Tasman regulator can be summarized into three major concerns:

1. The proposal would mean a **loss of New Zealand sovereignty**. Our Parliament would no longer have total control in this area and there are serious questions how matters specific to NZ like the Treaty of Waitangi, Official Information Act and our own Court system would retain their status under the proposal.

2. It is **inappropriate to use a pharmaceutical regulator** to control natural health products like dietary supplements. This doesn't recognise the vastly differing risk profiles of the two types of products, the different philosophical approaches and the economic differences between the two industries.

3. The Australian TGA is out of control and would impose an **enormous and unwarranted cost burden on local industry** without showing any increase in public safety as a result. For consumers this would mean **increased prices and reduced choice.**

The New Zealand Health Trust is at the forefront of opposition to the proposal and is the peak representative group for natural health consumers and industry.

LOSS OF SOVEREIGNTY

- The proposed body is without precedent and goes further than any other joint agency.
- As an international organization the regulator wouldn't need to comply with many local controls.
- If our MP's wanted to modify any rules of the agency they would be told they have no power to do so.
- The agency may not be answerable to the NZ courts.
- It is questionable whether indigenous interests under the Treaty of Waitangi could be properly observed.
- Decisions about using world guidelines such as Codex would not be made by NZ but by this new regulator.

INAPPROPRIATE PHARMACEUTICAL REGULATION

- The extreme regulation and testing regimes that have been designed for pharmaceuticals are not justified in respect of dietary supplements.
- The risk profile of natural health products is classed as being lower than that of food.
- To impose such regimes on these products is without justification related to risk and imposes an unnecessary compliance cost burden.
- Where safety issues have been raised in relation to natural products this almost inevitably results from products that include illegal ingredients. Those products already breach the law and as such the issue is one of enforcement.

- Unlike pharmaceuticals, dietary supplements are not patentable therefore a single producer cannot hope to recover all development and regulatory costs through a protected monopoly during the life of the patent.
- The same financial models cannot be used for the two quite distinct industries and regulation must be approached with this important distinction in mind.

COST BURDEN ON LOCAL INDUSTRY

- The proposal would see a system like the current Australian TGA apply to NZ.
- The TGA is widely criticized in Australia, was responsible for the Pan debacle, has been accused of protecting and preferring pharmaceutical interests and has not improved the public safety of consumers.
- The costs to businesses under the TGA are staggering and are **increasing even further** under a proposed new law, fines of up to **$550,000 for a company plus $55,000 for each director** will be able to be imposed by simple infringement notice.
- The proposal would see Australian businesses gain a competitive advantage over their New Zealand counterparts.
- The TGA brings with it enormous costs to businesses and huge discretionary powers of application and enforcement which can be used to punish anyone who displeases them.
- The dietary supplements industry in NZ is characterized by a high proportion of small to medium enterprises and many of them are predicted to close as a result of the substantial increase in compliance costs.
- By the time the exact detail of compliance costs under the proposed new agency is known (including indirect costs such as consultant's fees, time to market delays and the like) it would be too late to avoid the TGA assuming jurisdiction over New Zealand.
- The result would be higher prices to consumers, reduced choice, loss of innovation and the death of many New Zealand businesses.

CONCLUSION

The proposed Agency is 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. 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.

All evidence points to the system imposing a compliance cost burden on local business that will force many of them to close their doors and which is unwarranted given the actual risk profile of the products in question.

To preserve our rights to high quality and affordable natural products we must defeat this proposal. Once these rights are given away it will be too late.

Show your support by completing the "Vitamins Aren't Drugs" postcards and by joining New Health New Zealand Incorporated.

To order postcards, join New Health NZ Inc or to get more information visit our website www.nzhealthtrust.co.nz or phone Dave on 03 351 9807

New Zealand Health Trust
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