



Green Party's Submission Guide for Therapeutic Products and Medicines Bill

Submissions due on February 7th 2007

- Please take time to write an individual submission.
- Your submission doesn't have to be lengthy
- **Two copies** of your submission should be sent to: The Clerk, Government and Administration Select Committee, Parliament Buildings, Wellington.
- Indicate whether you wish to be heard in person at the Select Committee.
- The Select Committee will spend the next few months hearing submissions on the Bill, and will report the bill back to the House by April 30 2007. After that the Bill will have its second and third readings in Parliament, and if passed by a majority of MP's in the House it will become law in this country.

Key Points You Might Like to Make in Your Submission

- **Australian regulations are excessive.** Australian natural health products are one of the most highly regulated in the world. If the Bill passes we join the Australia New Zealand Therapeutics Authority, the same regulations will apply to our natural health products, and this will inevitably increase the cost of natural health products, reduce consumer choice and close down most New Zealand small dietary supplements businesses who won't be able to afford the ongoing regulatory and compliance costs.
- **An inappropriate, pharmaceutical model** will be imposed on low risk natural health care products, and would result in increasing pharmaceutical control of natural health products. Natural health care products are extremely low risk compared to the toxicity of many prescribed synthetic pharmaceutical drugs. (The New Zealand Coroner concluded that in stark contrast with pharmaceutical drugs, no deaths have occurred in this country due to natural health products, and there have been few reported adverse effects).
- **Natural health products would be assumed to be unsafe.** The new system would change forever the legal status of natural health products. Instead of being assumed to be safe unless they contain unapproved ingredients (as at present), natural health products would be assumed to be *unsafe*, and therefore illegal, unless every ingredient in them has been approved by the new agency—at huge expense.
- **Many health products could become illegal.** Most Chinese herbs and Ayurvedic medicines, which have been used safely for centuries, are likely to become illegal, because they contain ingredients that are not on a 'permitted'

list, and even high quality products that have been approved by the American FDA will be effectively banned.

- **Bill undermines the sovereignty of the New Zealand Parliament.** If it passed into law, control of dietary supplements, pharmaceuticals and medical devices industries in New Zealand will transfer to the Australia New Zealand Therapeutics Products Authority –an offshore entity that will be set up under Australian law, and will be headquartered in Canberra, with an office in Wellington. Documents obtained under the OIA indicate that about 93% of the staff of the agency will be Australians, and just 7% New Zealanders.
- **Decisions will be made privately and without public input.** There will be a Ministerial Council comprising the Ministers of Health of New Zealand and Australia, who will oversee the agency. However the two Ministers will meet in secret to review the agency. The main powers of the agency will be delegated to an unelected and unofficial ‘Managing Director’ who will have statutory powers of delegated legislation presently exercised by the Minister of Health, as well as powers to enforce and police regulations.
- **Excessive police powers.** Inspectors or police from the off-shore entity will have the power to issue warrants and prosecute people and organisations here in New Zealand, and close down dietary supplements companies.
- **Excessive legal powers.** The Managing Director will have the power to issue civil penalty and other offences, and to impose instant fines of up to \$550,000 on a company. As well as the instant fines, penalties for offences range up to \$5.5 million for companies as well as up to \$550,000 for every director and senior manager, and jail sentences of up to five years.
- **No justification for this bill.** Nowhere in the bill does the Government explain why it believes the natural health products industry in New Zealand should be subjected to this excessive and bureaucratic regulatory regime. (We believe their main is to enhance relations with Australia).
- **The system is already failing in Australia.** According to Australian sources, the Australian regulatory system for complementary medicines (through the existing Australian Therapeutic Goods Authority) has been an abject failure, and has done considerable harm already to the Australian natural health industry.
- **Compliance costs for small businesses will increase.** The government admits compliance costs for small complementary health businesses will increase.
- **No rigorous risk analysis.** There has been no rigorous risk analysis about the costs and benefits of the excessive regulatory and compliance regime proposed under the joint agency, or even a proper Regulatory Impact Statement.

For more information contact

Sue Kedgley MP, Green Party of Aotearoa New Zealand

Ph: 04-470-6717 Fax: 04-472-6003

Email: sue.kedgley@parliament.govt.nz

To:
The Clerk
Government and Administration Select Committee,
Parliament Buildings,
Wellington
(2 copies)

Submission to the Therapeutic Products and Medicines Bill

I wish / do not wish to be heard in person at the Select Committee

Signed _____ Name _____
 Address _____
 Tel. _____ Email _____