

## Minority report by Green party

We oppose the bill because we believe it will reduce New Zealander's access to many dietary supplements and traditional medicines, reduce consumer choice, increase compliance costs of natural health products and result in the closure of many small New Zealand businesses. We also have serious constitutional concerns with the proposed regulatory regime, which we believe will undermine the sovereignty of our Parliament.

The bill would implement in its entirety and without alteration, the 2003 Agreement signed between the Governments of New Zealand and Australia on 11 December 2003. Under the agreement, New Zealand will surrender its control of the natural products industry (along with pharmaceuticals and medical devices) to the Australia New Zealand Therapeutics Products Authority –an offshore entity that will be set up under Australian law. We were provided with evidence which indicates that the majority of the staff of the new agency will be Australian.

We believe the proposed agency would be, in reality, an extension of the existing Australian regulator, which uses a heavy handed, pharmaceutical model of regulation which is inappropriate for low risk natural medicines, many of which have been used safely for centuries. We note from the Coroner's recent report that there have been no deaths attributed to dietary supplements in New Zealand, and few adverse events.

We were provided with evidence that the Australian regulatory system has hamstrung and hobbled the industry, reduced innovation in the industry and the range of products available to consumers, and that high compliance costs are driving some dietary supplements businesses offshore.

We are concerned that the select committee had very little information before it about how the agency will operate. None of the governance and administrative arrangements of the joint regulatory agency are spelled out in the legislation. All the details of how the agency will operate will be set out in Rules and Orders, which will be adopted *after* the legislation has been adopted. These Rules and Orders will determine all sorts of key policy matters, such as what ingredients will be permitted in dietary supplements, licensing provisions, compliance costs etc. This means that Parliament is being asked to approve an unprecedented new regulatory system, which will be set up under Australian legislation, when it has very little detail before it on how the system will operate.

We note that the Australian regulator has identified more than 700 ingredients that are widely used in New Zealand, that are not on the Australian 'permitted' list. We still don't know how many of these will be approved by the new regulator

and how many wont make it through the system and will therefore become illegal.

We are concerned that the two Ministers who will meet periodically in a Ministerial Council to oversee the agency, will meet in private, and so the public will have no way of knowing what decisions are made by the two Ministers in the Ministerial Council, beyond what they choose to make public. The Minister has turned down repeated requests, made under the Official Information Act, for minutes of Ministerial Council meetings and has refused a request to provide this information to the Government and Administration Select committee.

The two Ministers, meeting in private, not our Parliament, will review the agency. The agency is not subject to key legislation such as the Public Finances Act. And the main powers of the agency, to issue Orders, 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.

The Managing Director's wide ranging powers to make regulations will, in practice, enable him to determine significant matters of policy and substance that should be the reserve of primary legislation and subject to the full and unlimited scrutiny of the House. The Managing Director will be, in a practical sense, the person who determines the regulatory environment for all therapeutic products in New Zealand and Australia, and his orders will determine the day to day environment in which New Zealand businesses will operate.

The agency will have unprecedented police powers of search and seizure without a warrant. This means that inspectors or police from the agency will have the power to prosecute people and organisations in New Zealand and close down dietary supplements companies they believe to be non-compliant, without a warrant, on suspicion of 'non-compliance.'

The agency will also 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 instant fines, penalties for offences range up to \$5.5 million for companies.

If the bill is passed into law, New Zealand will have no direct control over the regulation of therapeutic products except through an extremely limited disallowance regime. Under this regime, Rules and Orders issued by the agency could, technically, be challenged by a 'disallowance motion' in Parliament, but the reality is that a disallowance motion has never passed in the 153 year history of our Parliament. This means that the power to challenge regulations in our Parliament is essentially illusory.

Furthermore, regulations will be contained in one omnibus set of rules, and there will be no ability to reject or amend regulations in part, only to throw out the

whole set of rules, which further weakens this regime. Tight timeframes of 21 sitting days have been imposed on the regime, which do not apply to New Zealand regulations.

The agency will circumvent the Treaty of Waitangi. Under the legislation, the ability of tangata whenua to commercialise traditional rongoā will be decided by an international regulatory without any obligation to recognise Treaty of Waitangi obligations.

For most decisions, the only recourse to an affected party would be to bring judicial review proceedings, which are extremely costly and have extremely limited grounds of consideration.

We are concerned that the proposed new regulatory system would change the legal status of traditional herbs and dietary supplements. At present they are assumed to be safe unless they contain ingredients that are on a 'negative' list in New Zealand. Under the proposed system, any natural health product or traditional remedy that was not on an approved list would become illegal. This will mean that many traditional medicines such as Chinese and Ayurvedic herbs (even ones that have been approved by regulators such as the American FDA and safely used for centuries) will become illegal once the transitional stages have been completed.

The new regulations will also profoundly affect natural health practitioners, because they are likely to wipe out some of their tools of trade –the products they use to treat people—and hence their ability to practice.

In conclusion, we believe that dietary supplements and natural health products provide a valuable and beneficial addition to many people's diets, especially those who are deficient in certain minerals and vitamins. They help to keep people well and ward off ill-health and disease, and therefore reduce the number of people requiring treatment by our health system.

Recent research suggests that many New Zealanders are deficient in key nutrients, and as a result the government is considering mandatory fortification of our food with some nutrients. This suggests a need to facilitate, not restrict, access to dietary supplements in New Zealand.

We believe consumers need to be confident of the safety of natural health products, and that they should be regulated by a New Zealand based regulatory system which is appropriate for low-risk products. The elements of such a system are outlined in the Health Select committee report on its inquiry into how best to regulate dietary supplements.

We note that the whole point of pursuing Trans-Tasman mutual recognition with Australia through Closer Economic Relationships was to benefit New Zealand

businesses and consumers by *eliminating regulatory impediments to trade* with Australia. Yet the effect of 'harmonising' with Australia through this joint agency will be to impose onerous new regulations on dietary supplements which will have the effect of reducing the number of New Zealand owned businesses competing in this marketplace, and giving a competitive advantage to large Australian owned companies. We do not believe this is in the national interest of New Zealand.