Complementary Health Newsletter

by Sue Kedgley

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Hi Everyone,

Submissions on the Therapeutic Products and Medicines Bill due on February 7th 2007

This is to remind you to send in your submission on the Therapeutic Products and Medicines Bill by February 7th. You will recall that the bill narrowly passed its first reading in Parliament late last year, supported by Labour, New Zealand First and United Future MPs, and it is now being considered by the Government Administration Select Committee.

I have suggested (below) some key points that you may wish to consider in writing your submission. The New Zealand Health Trust is also doing an analysis of the Bill, which will be published on its website in the next few days – www.nzhealthtrust.co.nz .

It is really important that as many people as possible take the time to write an individual submission, rather than just sending in form submissions, which MPs tend to discount.

Your submission doesn't have to be lengthy and should just cover some of the key points you want to make to MPs.

Two copies of your submission should be sent to:

The Clerk
Government and Administration Select Committee
Parliament Buildings
Wellington.

You should 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.

However, a similar bill that will set the agency up in Australia has not even been tabled or introduced into the Australian parliament yet. So it looks as if the intention is that we will pass legislation in New Zealand **before** the Australian Parliament has even considered its bill. Presumably the Australian Parliament could make changes that would affect the way the agency operates, *after* we have passed legislation in New Zealand! This is of real concern, especially since the agency will be set up under Australian, not New Zealand, legislation.

Public Meetings on the Therapeutic Products and Medicines bill delayed.
We have decided to delay holding public meetings on the Bill for a few weeks, until the Select Committee is considering the Bill. This will also give people more time to concentrate on getting their submissions in by 7 February, and hopefully generate more interest in the public meetings when they are held.

The first public meeting will be in Auckland, and we will let you know details of venue and time well in advance.

Key Points on the bill
*Australian natural health products are one of the most highly regulated in the world. If the Bill passes through Parliament and we join the Australia New Zealand Therapeutics Authority, the same draconian 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 wont be able to afford the ongoing regulatory and compliance costs)

*It will impose an inappropriate, pharmaceutical model for low risk natural health care products, and would result in increasing pharmaceutical control of natural health products. It is not appropriate, in our view, to use a pharmaceutical model to regulate and evaluate dietary supplements which are extremely low risk compared to the toxicity of many prescribed synthetic pharmaceutical drugs. (The New Zealand Coroner undertook extensive research into natural medicines recently and 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).

*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.

*As a result, once the new system is fully in place, in about five years time, many herbal products presently available in New Zealand could become illegal. Most Chinese herbs and Ayuvedic 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. We will inevitably end up with far more Australian products and very few New Zealand products on our shelves.

* The Bill will undermine the sovereignty of the New Zealand Parliament. If 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. It will be the first time entire industries in New Zealand will be controlled by an off-shore entity located in another country. Documents I have obtained under the Official Information Act indicate that about 93% of the staff of the agency will be Australians, and just 7% New Zealanders. This speaks volumes about how 'equal' this agency will be.

* Sure, there will be a Ministerial Council comprising the Ministers of Health of New Zealand and Australia, who will oversee the agency. But the two Ministers will meet in private and we will have no way of knowing what they discuss or approve, beyond what they choose to make public. The two Ministers, meeting in secret, not our Parliament, will review the agency. And the main powers of the agency, to issue 'Orders' on all manner of matters, 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 agency will have unprecedented police powers of search and seizure. This means that 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. Sounds Orwellian? It certainly does.

*The unelected and unaccountable 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 $550,00 for every director and senior manager, and jail sentences of up to five years.

*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.

Background on the bill

The Therapeutic Products and Medicines bill will set up the new agency, now

called the Australia New Zealand Therapeutic Products Authority (ANZTPA). The Bill can be found on the Parliament website at http://www.parliament.nz/en-NZ/PB/Legislation/Bills/1/5/8/158f6594b0e74acf89fee18dd11c0f92.htm

I wouldn't bother trying to wade through the 383 page Bill though, as most of it deals with issues other than the establishment of the new agency.

In fact the Bill states quite clearly that all it does is give effect to the provisions of a Treaty that the government signed with Australia way back in 2003. That Treaty sets out all the governance and administrative arrangements of the joint regulatory agency, and despite claims by Winston Peters and the Government that changes that have been made to make the agency more acceptable, there have in fact been no significant changes since the Treaty was signed in 2003.

The Bill also acknowledges that 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 passed**! These Rules and Orders will determine all sorts of key matters, such as what ingredients will be permitted in dietary supplements, compliance costs, licensing provisions etc. A consultation document on the Managing Directors Orders is not even expected to be released until March – well after submissions on the Bill have closed!

These Rules and Orders will have 'the force of law' in New Zealand, but will not require the approval of our Parliament. The Managing Director of the proposed agency will have the power to enforce and police these Rules and Orders in New Zealand, even though they will not have been voted on by our Parliament.

Technically the Rules and Orders could be challenged by a 'disallowance motion' in Parliament, but this is highly unlikely as a disallowance motion has never passed in the 153 year history of our Parliament.

What all this means is that none of the detail of how the agency will operate is contained in the Bill (though we know it is likely to operate in the same draconian manner as the present TGA does) so MP's will be voting to set up a new system and agency they know very little about.

The **main purpose of the Bill is to give effect to the Treaty and to hand over the jurisdiction and control** of the pharmaceutical, medical devices and dietary supplements industries in New Zealand from our Parliament to the off-shore entity known as ANZPTA.

Other Key Points:

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. Which begs the question, why would we want to adopt a system which is considered a failure in Australia?

Val Johansen, a key player in the complementary medicines industry in Australia, says the TGA's excessive and bureaucratic regulatory system has hamstrung and hobbled the industry there. She says the excessively high compliance costs (which have been increasing by more than 15% a year) are driving businesses offshore. Because of the high cost of getting a product or new ingredient licensed, there have been very few new products coming into Australia and consumers there have access to a much restricted range of supplements (mostly made by large multinational corporations who can afford the high compliance costs).

Professor Ian Brighthope, President of the Australasian College of Nutritional and Environmental Medicine, says the TGA has treated the natural health industry there with contempt. He says there is a widespread view that the agency is controlled by pharmaceutical interests and has a bias against natural healthcare.

Essential for Trans Tasman Cooperation?

The main reason the Government is now giving for ramming the legislation through Parliament is to enhance CER, closer economic relations, with Australia. Clearly, the Australians are playing hard-ball over the proposed agency, and are threatening to halt all further moves for greater economic integration *unless* New Zealand agrees to the joint agency.

The well-connected columnist Colin James said as much in a recent New Zealand Herald column: "Canberra has made it clear there is far more at stake than the agency alone, he reported in a recent column. "What is at stake is goodwill. .. rejecting the agency would discourage Australia from committing the bureaucratic time to similar future joint agencies. More important, the hard word in Canberra is that it would potentially make it harder to get traction on other elements of the single economic market.

New Zealand MP's have been lobbied intensively on the Bill, including by the Australian Minister of Foreign Affairs and the Federal Minister of Health, who slipped into Wellington unannounced for a week last year to lobby various MP's on the agency.

The Prime Minister said recently that if New Zealand doesn't give the green light to the agency, it would "adversely affect the overall agenda of deepening economic cooperation and integration between Australia and New Zealand."

Along the same lines, the Minister in charge of the agency, Annette King, wrote recently that the new agency, which will be 'the first example of a true Trans-Tasman authority,' will set a precedent for increased trans-Tasman co-operation that explicitly acknowledges joint co-operation of two independent nations."

But it is worth remembering 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. But the effect of 'harmonising' with Australia through this joint agency will be to **increase compliance costs** and regulatory impediments for New Zealand businesses, and these will be passed onto consumers as higher costs.

The Bill violates Government's own commitment to reduce compliance costs for small business.

The government says one of its key priorities is to reduce compliance costs for small businesses. Minister for Small Business Lianne Dalziel, said in a recent speech in Parliament: "reducing compliance costs (for small business) is an objective which is an important part of the government's wider business law reform programme and economic transformation agenda."

The government set up a Ministerial Panel on Compliance costs to try to reduce unnecessary compliance costs on small business, and is presently examining business 'regulatory frameworks' and how they impact on small businesses. One of the purposes of the Quality Regulation Review is to ensure that 'regulatory frameworks or their enforcement are not acting as a barrier to growth'. Yet here the Government is seeking to pass legislation that it admits will significantly increase compliance and regulatory costs for small businesses who produce or import low-risk dietary supplements!

The Government also says it wants 'more rigorous risk analysis when developing and enforcing laws'. But 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.

Regards

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'Let Food Be Thy Medicine and Medicine Be Thy Food' Hippocrates 400 BC