

Just how close should Australia & New Zealand get?

Closer Economic Relations (CER) is put on notice

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Good afternoon. As you've heard, my name is Amy Adams, and I'm a partner in the New Zealand law firm Simon Mortlock Partners and spokesperson for the New Zealand Health Trust

I've been asked to speak to you from a New Zealand perspective about the implementation of the Trans Tasman Agency to regulate therapeutic products and medical devices.

However there is a problem with that subject, namely there is a great deal of doubt as to whether it will ever happen.

So I thought I'd explain what is proposed, why it's been put forward as it has, why there is strong political, consumer and industry opposition to it, and what happens next.

My paper focuses on the regulation of natural or complementary health products because this is the industry that is expected to feel the greatest change under the proposal.

And it is this industry that has been leading the opposition to the proposal in New Zealand.

To a large extent it has to be said that the proposed joint agency is unlikely to change day to day regulation in Australia to any noticeable degree. In effect the new agency appears to be little more than the TGA extending its reach to include New Zealand albeit under a new name and management framework.

My role today is to detail how the agency would represent a quantum change in New Zealand. You may wonder why you should be concerned with the effect of this in NZ and the answer to that is two fold. Firstly this issue has the makings of a political storm and secondly so that you can understand the reason for New Zealand's opposition to the proposal and just why it may see the joint agency defeated.

The New Zealand Health Trust is a charitable trust whose objective are to ensure that good health options and quality health information are available to everyone. The Trust has primarily been interested in the proposed Trans Tasman joint

regulator from the perspective of the impact it would have on the natural health industry in NZ. That industry is characterised by predominantly small to medium sized businesses, generally producing for the local market although of course we have a small number of larger companies that export widely.

The Trust spent a number of months working with the NZ Natural Health industry to assess what impact the proposal would have and was horrified to find that the majority of manufacturers and significant numbers of practitioners would be driven out of business should this proposal proceed and the products that did remain available were likely to substantially increase in cost to the consumer.

In this case the Trust felt that the downside was just far too significant for the consumers and industry for it to go ahead.

We spent many, many months working with the NZ Minister of Health and officials showing them the problems it would create, but it fell on deaf ears as they appeared determined to proceed at all costs.

It has taken a long time to get to the bottom of what's driving this urge from our Government to effectively push the New Zealand natural health sector off a cliff..

However it has become clear that our Government is being bullied by the Australian Government into going down this road, despite everything pointing to it being a dreadful idea for New Zealand.

Our MP's are being told that this is critical to the relationship between our two countries, and if we don't tow the line, CER is... if not deadcertainly on life support.

Now .. if the Australian regulatory system was world-leading we perhaps wouldn't have a problem climbing on board with your regulations. But, speaking frankly here, we know it's not. In fact it is acknowledged by your own natural health industry, overseas officials and many in the media as bureaucracy gone berserk and disastrous for businesses and consumers alike.

So having failed to convince the NZ Minister to change her mind, the Trust was forced to take a different political route, and worked individually with the 6 opposition parties to explain the problems the proposal would create. Those parties agreed with our view, and have so far refused to support the minority NZ Government on this issue.

But before I get ahead of myself lets quickly run through what this presentation will cover (slides)

CURRENT REGULATION

In New Zealand the sector is governed by two pieces of legislation from the early 1980s – the Dietary Supplements Regulations and the Food Act. Until now natural health products have been a subset of foods. This proposal would make them a subset of pharmaceuticals which is a major philosophical change.

These are sporadically enforced and are widely accepted by both industry and government as inadequate. This needs to be emphasized. The opposition from NZ to the new Agency is in no way an opposition to good and effective regulation. The NZ industry is the first to agree that new and comprehensive regulation is needed. The dispute is simply over how we go about it..

In 2000, after a long period of consultation with the industry, a new set of regulations was developed in the Healthcare and Therapeutics Products Bill 2000, which prescribed a detailed risk based system that protected consumers and the industry alike.

This model received general industry acceptance. It was all set to proceed, when it was abruptly withdrawn by the NZ Government when it announced from nowhere its intention to proceed down the Trans-Tasman Agency route.

The other piece of relevant law here is the Trans Tasman Mutual Recognition Act 1997 which sets out how CER is to work between our two countries. That is by a system of mutual recognition of goods. What is acceptable under the rules of one country should be acceptable for sale in the other country... both NZ and Australia recognising and respecting the other's capabilities and entitlement to make their own decisions.

This is in fact how CER has been affected – until now.
I'll return to this later.

The GOVERNMENT's PROPOSAL

Our governments have agreed by a treaty signed last year to create a Trans Tasman Agency to regulate ALL therapeutic products and medical devices.

From New Zealand what is clear is that the agency is nothing more than the TGA extending its reach to New Zealand. In one way NZ is fortunate as we only have to look at Australia to have a working model of just how the system would work.

For Australia it will mean that the TGA will have wider application throughout the states than it does currently.

What has become clear is that under a Trans Tasman regulator nothing of importance will change. Your TGA has not spent more than 10 years making the system tougher and tougher on natural products only to loosen the controls now.

The Treaty and working papers declare that the proposed agency would control all therapeutic products.. that is anything taken for therapeutic purposes. Whilst we all know that the definition will include all pharmaceuticals natural health products and medical devices, the width of the definition means that technically it also includes all vegetables, fish, water and even oxygen. This means the final decisions as to where lines will be drawn will be unknown and left the whim of agency staff.

Its scope means that products coming under the TGA would include vitamins, minerals, food extracts and the like. Products that have a far longer history of use, with miniscule risk profiles, would become subjected to the pharmaceutically-inspired compliance protocols of the TGA.

It will operate under a Ministerial Council made up of the New Zealand and Australian Health Ministers, with an Agency Board and an all powerful Managing Director. Importantly the Managing Director is not a public servant and does not report to the agency board. Once this person is appointed they have full operational authority and delegated legislative powers to make the rules and set the fees and penalties.

Furthermore – the Treaty expressly provides that the Managing Director may sub-delegate any of his or her powers to any other person who may not necessarily have the approval of both health ministers.

It will aim for full cost recovery from industry and have extensive powers of enforcement

The treaty also makes clear that the agency may itself cede its powers to control therapeutic products in both our countries to some other international body thereby diluting Australian and New Zealand control even further.

Other key features of the proposed agency are it will operate from a “white list” approach – which means an ingredient is prohibited unless it is on a ‘safe list’. As a result, the first party to apply to have a new product added to the list carries all the cost of the approval process

It includes provision for pre-vetting of all advertisements and it has lesser requirements for so-called “lower risk” products without giving any detail of which products may qualify for this lesser test and how much “lesser” these requirements would be.

We see this is an attempt to lull the Natural Health Industry into a sense of complacency without actually lessening the bureaucracy to any great degree.

Decisions of the agency will be subject to review by a merits review panel and MAY be permitted to be further reviewed by the court system in each country. The Merit review panel concept is less impressive when it is realised that the

people appointing that panel are the same people behind the agency and who appoint the agencies key staff, raising serious questions to its independence and objectivity

This proposal is one of HARMONISATION not mutual recognition. Instead of the two countries recognising and respecting the stand alone operation of each other, as was the agreed basis of C.E.R., Australia has demanded that New Zealand adopt its system or face a trade barrier for our goods.

Quite apart from the WTO issues that attitude raises, we see enormous practical difficulties with the model proposed.

Principally in New Zealand it means hugely increased compliance costs – one estimate has costs to register a product leaping from approximately \$17,000 to \$70,000 without allowance for the considerable indirect and time to market costs.

Independent economic analysis shows that the products of the companies that survive are likely to substantially increase in cost as compliance costs are necessarily passed to the consumer.

Never will the cost of keeping yourself healthy been so high.

And quite apart from cost, everyone agrees that the proposal will limit consumer options in NZ. As a number of products won't comply with the white list (products that many NZ'ers have used for years and have come to rely on) or as NZ companies cease to be able to survive under the impossible burden of TGA compliance costs then these products will cease to be available on the market. Additionally many practitioners will head overseas.

Further we would strongly argue that a pharmaceutical model is simply inappropriate for natural health products, which are known as a category to be largely harmless. Increasingly we see internationally that these products are being recognised as a separate third category distinct from both medicines and foods.

Whilst pharmaceuticals, even under stringent regulators, are recognised as having a far higher risk profile, natural health products, even in countries where they are largely unregulated, simply are not causing anywhere near the same levels of harm.

This is of course the key reason why an ever increasing number of consumers are turning to natural alternatives.

So not only are natural health products and pharmaceuticals quite separate and distinct industries with their own expertise and approaches, they are increasingly competing industries. To force them under one regulatory umbrella is repugnant.

Constitutionally and politically the proposal is fraught with problems.

This body would be a new type of beast – we have never tried a system of one regulator

subject to the laws and courts of two different countries in this way.

The proposal has been analysed by some of the leading constitutional minds and they have reported they foresee very real and serious issues that could arise.

To take just one example of the problems let's say that a decision of the agency is taken to the Courts in both countries to review and those two legal systems come up with quite different answers. Does the rule then apply in one country but not the other? This would destroy the common set of rules overnight.

Or, what if one country wants to make a change and the other doesn't. That means each of our Parliaments lose the right to have absolute control within their own country.

As you can see, constitutionally it is serious stuff.

Another problem revolves around the encouragement of innovation. As I've already touched on given the white list system, the first party to seek to develop a new product or idea is burdened with the overwhelming cost of approval. For pharmaceuticals this is appropriate and ties in with the rewards that flow to that business through the patent protection they are entitled to. Natural Products however are not patented removing the economic sense in being the first to put a new product on the market.

The effect of this is the death of innovation.

In New Zealand we currently operate a black list system such that if it isn't banned or controlled and isn't a pharmaceutical, it can be used. The onus is on the regulator to list unsafe products, rather than on the first industry player to prove their safety. Once again we would argue this is quite appropriate given the low inherent risks of natural products that have in many cases been in use for hundreds of years.

The Australian experience also demonstrates that the system works as an effective NTB or non-tariff trade barrier, which is of course illegal under the provisions of the WTO, and hampers importers' ability to make the products of other countries available to consumers.

As mentioned, the Treaty not only does not protect local input, but specifically enables the agency to itself cede its control to a larger international body which

would dilute local input even further and make it all but impossible for stakeholders in either of our countries to have their concerns heard and addressed.

There are also problems with the potential for cross industry subsidisation at the expense of the natural health product sector.

As already mentioned, these industries are in many cases in direct competition for the consumer dollar. Under one regulator with global cost recovery, should another Pan pharmaceuticals situation arise, the natural health industry could be left footing a substantial bill for what was at its heart a pharmaceutical failing.

Where the TGA has failed to protect consumers from faulty heart valves and dangerous pharmaceuticals, it faces huge potential lawsuits. The natural health industry in New Zealand is understandably not keen to make itself liable to help fund such problems.

In addition, provisions give the new agency wide discretionary powers which create a disastrous lack of certainty for businesses trying to operate in the sector and only serve to increase the cost of doing business.

I've already outlined how the TGA system would impose a hugely increased compliance regime on the New Zealand natural health sector which were it justified by actual risk information might be ok, but it is not.

It appears to be bureaucracy for the sake of bureaucracy and this is borne out by the many individuals I've spoken with from across the Australian health sector who have recounted countless horror stories about operating under the TGA. What is more, recent information out of Australia indicates that your public have had no appreciable increase in safety as a result.

Clearly this proposal isn't going to work for New Zealand. Instead of being shoe-horned into this Australian system, we believe that mutual recognition is the way to go, keeping with the true nature of C.E.R as it was designed to work. Our countries stay separate and distinct, having full control of their own industries, but we open our borders to each other as a mark of mutual respect.

But as you might expect, everything hinges on the politics of this issue. And in this case it's really all about Trans Tasman relations and Trade.

It's very little to do with safety, the consumers or even health products! Its about Australia demanding that we joining its system if we want to trade with you.

Late last year, the New Zealand and Australian governments signed a Treaty agreeing to put the Trans Tasman Agency into place. Both countries agreed to pass legislation enabling the Treaty by the end of this year. Despite what our

health minister tells the public, the media and the Australian government, it's far from a done deal.

The Minister has some significant political problems to overcome if she wants to pass this legislation. So far, this plan has been before Parliament's Health Select Committee twice. Both times it has received a resounding 'NO!' from the MP's. All the opposition parties are committed to opposing the legislation enabling the new Agency.

It would clearly be an embarrassment for the NZ Government if they couldn't pass this legislation. Under huge pressure for the Australian Trade officials the Government is working very hard to turn the political situation around. We have no doubt they will do everything they can to get the numbers on side to push it through. But we have a minority government so at the moment the NZ Minister needs the co-operation of other parties to pass it.

Thankfully, the majority of the New Zealand Parliament agrees with NZ Health Trust that the Trans Tasman Agency would be a disaster for New Zealand consumers and businesses. You would have to say that it will be difficult, if not impossible to pass the legislation enabling it.

NZ has committed to pass the legislation before Christmas. However there are only another 10 – 20 sitting days left this year, and a huge backlog of bills the NZ Government wants to pass. So we think it unlikely that the timeframe commitment will be met.

The fact that there is such strong opposition in New Zealand appears to have come as a surprise to the Australian Government who are presumably being assured that everything is on track.

However, there are two wider and more important issues underlying this natural health products debate that I would like to briefly mention before I wrap up.

Firstly, in Australia it seems that you are very good at having national conversations about important constitutional changes such as becoming a Republic or not. But in New Zealand we are unable to have these discussions as a nation.

The current Government has a strong conviction that it knows what is best for the public, and it makes fundamental changes unilaterally and without meaningful consultation. Abolishing the relationship between New Zealand and the Privy Council is a prime example of a major constitutional change driven through in the face of massive public opposition.

In addition, there are other significant areas where Australian regulatory systems are being proposed for New Zealand without meaningful debate (Banking & Securities to name a few).

We strongly believe that the New Zealand public has not had a chance to consider the implications of this and other 'incremental' changes to our constitutional law system.

Those of us who have thought it through are beginning to fear waking up one day to find that NZ is an Australian state in all but name!.

Now we are NOT opposed to moving closer to or even to joining up with Australia if the NZ public decides it is a good idea. But both Governments should be on notice that New Zealanders will not put up with it being imposed by stealth.

The second issue is one of fairness.

Our government is constantly telling us that this is a CER issue and we must show good faith in the trade relationship. Let me point out that Australia has not got a good reputation for fairness when it comes to trade with it's next-door neighbour.

As recently as two weeks ago major NZ newspapers ran front page stories detailing some of the examples where Australia has chosen to ignore its part of the C.E.R deal

A few examples;

- Open skies agreements
- Residency entitlements
- Stock exchange rules
- US free trade talks
- Wine rebates
- Tax on bank profits
- And most recently, - Apples

Frankly, it looks very much as though Australia ignores CER when it suits, but insists on it when Australia will win at NZ's expense.

We do not plan to allow the natural health products sector go the way of the Apple Industry and others which are presently preparing their cases to go to the WTO.

So for the New Zealand Health Trust, the battle is a long way from over.

We have spearheaded a concerted effort from the public and industry to ensure this opposition remains very visible to politicians and officials. We've had petitions with tens of thousands of signatures presented to Parliament. Individual MP's have received thousands and thousands of emails urging them not to

support the legislation. And we've been running a massive direct mail campaign with more than 100,000 postcards in circulation.

As at today the Labour Government simply does not have the numbers it needs to do what it has said it will do under the therapeutic products treaty. So the question is most definitely not how will the joint agency operate
But will it ever operate at all?

I am very aware that I'm keeping you all from your lunch so I'll close by saying the New Zealand industry is united in its desire for open trade with Australia and better regulation. It's not in our interest to have fly-by-night operators and misleading information going to consumers.

But just like every other part of the health industry, it's good regulation we want and regulation that has been driven by the right motivation.

Thank you.