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Submission

Therapeutic Products and Medicines Bill

I wish to be heard in support of this submission.

I fully support the submission that the NZ Health Trust and New Health NZ have presented and do not propose to cover the same detail here but make some observations that I hope are helpful for you to make the decision to reject this Bill as I do.
My interest is mainly Natural Health Products and Medical Devices.

1. The Gate Keepers of health regulations

My interest in this proposed Joint Agency with Australia dates back to 2001. For many years prior to that I had been researching how to achieve the best health out come for the individual. I observed that the Medical establishment is good at accident and emergency situations but has less answers for disease prevention and lacks the knowledge to keep people well on a sustainable basis. The problem is, as I see it, a tendency to have a closed mind and a tendency to treat anything new outside of its establishment as a threat.

It makes sense and stands to reason that in the future there is going to be new approaches to health that will very likely be out of keeping with the pharmaceutical model that this Bill enforces. As I see it the power of the proposed Managing Director is that of a sovereign Gate Keeper of health matters, the possibility of power corrupting (as has been written by others before) is very real. The understanding and knowledge that I have gained to date gives me visions of the previously mentioned possibility of a completely new approach to health matters. I am very concerned that this bill including the unknown regulations that the managing director imposes, would never let it or other similar innovations see the light of day in any useful way to help consumer's health. This is one of the reasons I have been opposing this proposal for many years.

I would mention that my opposition to this Bill is mainly from a consumer point of view - to ensure the best possible health outcomes and the maintenance of health choices and options. I support appropriate Laws and regulations in line with the risk involved - the same as the model in the NZ Health Trust / New Health submission which is based on the very same well canvassed principles that the Health Select Committee recommended in its report of December 03.

2. Unrealistic Time Constraints

I am extremely concerned at the extremely short time available to make this submission especially compared to other Bills of far lesser importance and with lesser implications to NZ and the people than this one. It is a very serious concern and has put an enormous pressure on the already stressed Natural Health industry and the aware consumer. This proposal has been hanging over the industry for many years and has caused a lot of feelings of injustice, and caused many well intentioned and innovative individuals to give up. This has been an undesirable loss to the health outcome and options for consumers.

3. Hidden Agenda?

In a press statement on the 11th of December 06 Helen Clark said this Treaty is a very early example of the wider strategy to harmonise regulations with Australia. Then, the following day Annette King said in the House that the Treaty was a blue Print for the future dealings with Australia.

If this is the case and I am reading it correctly, then shouldn't there have been an open debate about the real intentions instead of making up some unjustified story about concerns for quality and safety to consumers from Natural Health Products? And why was this plan not revealed at least 5 or 6 years ago?

4. Penalties

After talking to several people that have been in the industry for many years about this Bill the short answer is that if this Bill goes ahead then they will close their business or contract out to China, one stating the threat of the penalties are completely unacceptable and why would he risk his liberty and his family's financial future? (I totally agree)

One of the many reasons for Natural Health Products (NHP's) regulation to be completely separated from that of Pharmaceuticals is that the penalties for NHP's are totally unreasonable especially in line with their extremely good safety profile, but on the other hand Pharmaceuticals are infinitely more dangerous as history clearly shows, the penalties need to match their risk profile, so they need to be much larger to achieve that goal. The effect of this point is that the safe NHP industry will be doing the bidding for the reduction of penalties for the higher risk sector and this is not a sensible outcome.

5. Consumer focus

In my view Laws, Regulations and Policy should be designed and focused to achieve the best unbiased health outcome to the consumer. This Bill, in my opinion, will only produce the best health outcome for monopoly minded commercial and other vested interests and do very little for the consumer.

6. Corporate Monopolies

The book "Ten Days to an MBA" used by many thousands of students world wide to gain the necessary knowledge to obtain an MBA, teaches that the standard method to gain a corporate monopoly in a given industry is to push for massive over-regulations on the targeted industry. This will remove a lot of the competition and dramatically increase your market share because smaller competitors can not afford to comply with all the compliance rules and costs. The ultimate technique is to create a law (the same as this Bill does) that effectively allows all regulations to be made by a corporate managing director. These techniques are very essential where the products are not patentable and the raw materials needed are outside your control. Undesirable and over-regulations create decisions and outcomes that do not stand up to scrutiny in the light of day.

7. Product range Lost

In late 2006, representatives from the TGA and Medsafe had a meeting at the Copthorn Hotel (the one close by the Auckland Airport) with Natural Products NZ representatives and a few others. There was a presentation to those present to try to get agreement to a deal to support ANZTPA. There was an overhead projector in use and one of the screens used was the calculations of the financial and funding model for ANZTPA which predicted over 40% of the current products on the NZ market would disappear.

These products have been sold in NZ for many years and are not a health concern of any kind and obviously are of health benefit to the purchasers. So why does the promoters of this Bill now think they are too removed from the market, it is not a health issue, is it simply politics?

8. Report by Oceania Health Consulting Jan 05

Review of the need for further regulations of Extemporaneous Compounding.
This report shows a very real example of why the TGA in Australia is so keen for the Trans Tasman body, less to do with NZ and more about removing their constitutional inability to regulate sole traders and natural persons.
The report demonstrates that the TGA wants to extend its control to all States and Territories in Australia to cover natural people and extend control into pharmacies and hospital, all of which are currently outside their domain. It only currently covers 3 of the 8 States and Territories - being NSW, Tasmania, and to a lesser degree Victoria. I find it disturbing that NZ, via this Bill, is being used to over-ride the Australian constitution and natural person's rights.
Given these facts why would we in NZ want to be involved in the expansion of the TGA regime when the majority of the other states and territories obviously don't, they have had since 1992 to do so?
Please see Appendix 1.

9. Costs to NZ industry
I plan to follow up this submission prior to my appearance at the committee with an example product and the costs associated to manufacture and supply this product.
This is a very difficult mission because the rules that have been announced and this Bill do not contain all the costs involved to industry. So therefore the only option is to use the cost from Australia. A difficulty is that some of the ingredients are not allowed in Australia.
And again, because of the short timeframe for submissions over the Christmas holidays, I have not been able to complete this to send with this submission.
Please see Appendix 2.

10. Two previous Health Select Committee Reports

The Health Select Committee (HSC) thoroughly investigated the proposed Joint Trans-Tasman agency scheme for more than a year. The HSC, businesses and consumers spent massive amounts of time and at huge financial & personal cost. The outcome was in a report delivered on 13th of December 2003.

This HSC report was unanimously agreed and signed by all the 11 members of the committee including 5 Labour MP's. The report rejected the proposal and made some sensible recommendations. Annette King, with apparent total disregard for all the work and cost of the report, signed a treaty with her Australian equivalent Trish Worth on the 10th of December 2003 being less than a week before the public version of the HSC report was released.

Early 2004, submissions were again called for by the HSC on the Treaty that was signed on the 10th of Dec. and again a lot of time was spent by many people and the HSC MP's. Once again the HSC report released June 2004 rejected the Treaty. And once again, the report has been totally ignored by the Government.

Given that this Bill enforces the original proposal unchanged and the same applies to the Treaty, I respectively ask that the two HSC reports be acted upon and this Bill be rejected.

Thank you for your time and the opportunity to speak to you today.

Best Regards.

Dave Sloan

Appendix 1

2 The present legislative framework in Australia

The TG Act has the Object, in part, to *"...provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are ...used in Australia, whether produced in Australia or elsewhere; or exported from Australia".*

In pursuing this Object, the TG Act establishes controls on standards, advertising, sale or use (through registration) and on manufacturing practice.

Specific exemptions are provided from *some* of these activities through provisions in the TG Regulations. In particular Schedules 5 and 5A of the TG Regulations provide exemption from the need to register therapeutic goods under certain circumstances, and Schedule 8 provides, in effect, exemption from the need to comply with the Code of Good Manufacturing Practice under certain circumstances.

The detail of the exemptions provided in these Schedules of the TG Regulations is set out in Appendix 2.

2.1 Constitutional limitations of the Therapeutic Goods Act

The above exemptions are, however, irrelevant if the pharmacist (or medical practitioner) engaging in the practice of extemporaneous compounding is an unincorporated body trading within a State and not trading with the Commonwealth, as the Australian Constitution does not provide powers to regulate such persons at all (see section 6 of the TG Act).

Some States, notably NSW and Tasmania, have passed complementary legislation that applies the TG Act as if it were a law of the State, and Victoria adopted the TG Act in total, although over time the amendments to the TG Act have not been picked up in full so the legislation in Victoria now differs. Even in these jurisdictions, however, there have been difficulties in covering natural persons trading intrastate.

In South Australia a great many pharmacies are incorporated bodies, which means the Commonwealth would have jurisdiction over them but in any case, as a policy issue, the TGA wants to leave the regulation of pharmacies to the Pharmacy Boards and not to become involved in the regulation of pharmacy practice. If there was a complaint, however, with evidence of practices are in breach of the TG Act, TGA could act where the pharmacy is incorporated.

The limitations of the Australian Constitution will end once the trans-Tasman regulatory body is formed. The Treaty forming it will invoke the foreign affairs powers of the Constitution, which will then enable the regulation of natural persons in Australia. This report has taken the approach of assuming that this will occur in July 2005 and that changes can be made to the provision of the new legislation that parallels those in Schedules 5, 5A and 8 to regulate to the extent that is necessary, extemporaneous compounding by any person in Australia or New Zealand from that date.

It should be emphasised, however, that some of the practices reported to be currently happening appear to be in breach of the TG Act as it stands.

Appendix 2 (5 pages)

Notes for Presentation by John N Thomas to the NZ Government Administration Committee in Christchurch on 11th April, 2007 and in support of the submission by David Sloan.

Good Afternoon, Ladies and Gentlemen

I have been invited by David Sloan to review and compare the current New Zealand system and that proposed under the Joint Agency, as industry currently understand it to be, with regard to a number of existing New Zealand products. Given the significant disparity in the systems, this was a difficult exercise to undertake.

Introduction and Background

I have extensive experience in the following;

- Big Pharma in Australia
- Regional Marketing in Asia
- Exporting in the Complementary Healthcare Products (CHP's) industry
- Exposure to 3 Australian businesses coming to grips with the Australian regulatory system

I am not against regulation. Like most people in Australia, I only seek appropriate regulation - regulation appropriate to the risks posed by CHP's. If CHP's are classed as Low Risk (on the TGA white list), then treat them as Low Risk.

It is my firm belief that the Regulatory framework under the proposed Joint Agency would not be appropriate for Complementary Healthcare Products in New Zealand. The cost overheads that it would impose would be highly destructive to the local industry, leading to the closure of manufacturing facilities, the loss of a significant number of jobs (both in the manufacturing and retail sectors) as well as a large number of products that are currently available on the New Zealand market, and would have a significant impact on New Zealand's substantial export of CHP's.

A simpler, more streamlined system could be developed that would more than adequately meet the objective of protecting public health and safety. One example may be the New Zealand Government Health Select Committee Report, December 2003. Another may be the implementation of the Hazard Analysis and Critical Control Points (HACCP) or ISO Systems, both of which have International recognition, or a combination of both.

This submission outlines my views on the significant differences between the current New Zealand system and the proposed Joint Agency and the potential impact on local industry participants.

Review of NZ Products

Prior to my visit to New Zealand, I had the opportunity to review about 20 products from 4 reasonable sized New Zealand Sponsors (businesses). Under the Joint Agency, only 1 or 2 of these products would have been acceptable in their present formulation. The others would be unacceptable due to non-permitted ingredients, unacceptable levels of trace elements, use of Glandular ingredients, non-compliance with GMP etc. These would need varying amounts of reformulation to be eligible to reach the market and many to the point of being un-recognisable from their current “equivalent”.

Medsafe have stated publicly that they expect around 40% of products to disappear from the market if the Joint Agency proceeds. Based on this review, the actual percentage could be much higher.

It is reasonable to assume that the 3 or 4 largest Sponsors in the local market would have little trouble complying with the proposal as most already market or source their products from Australia. For the vast majority of the smaller industry players, however, it is highly likely that **all** would lose products, some to the extent of the majority of their range.

This would, I believe, significantly reduce the range of options available to consumers and at the same time, reduce innovation, as it is often the smaller players who need a different and innovative product to succeed in the market.

Factory Visits

In the last 36 hours, I have visited 3 factories manufacturing CHP’s for the New Zealand market. In my opinion, all would fail the GMP requirements of the Joint Agency. Two (2) have indicated that they would close if Joint Agency proceeds. One of these is quite a good sized local manufacturer, currently producing between 200 & 300 products. Their best selling products would not be acceptable under the Joint Agency.

For most of these products, typical batch sizes are currently between 5,000 - 75,000 tablets or capsules. Under the Joint Agency, batch sizes would have to increase to around 250,000 tablets or capsules to be economically viable as a result of the increased compliance costs. Their view is that the New Zealand Market is probably too small to justify this volume

The loss of these manufacturing capabilities would impact on employment and further reduce New Zealand’s capacity to be a self sufficient and innovative supply source.

Unjustified Compliance Costs to Manufacturers

The implementation of the Joint Agency would render most QA departments in New Zealand manufacturers totally inadequate to allow the enterprise to operate efficiently.

Most manufacturing facilities would need extensive re-fit or refurbishment of their facilities to comply with the GMP and Quality Assurance (QA) aspects for the proposed

Joint Agency. The costs would vary from company to company, and could range from $1 million to $10 million.

Quality Assurance costs would be significant if a manufacturer or Sponsor is to establish their own full function QA capability in order to meet the extensive requirements of the Joint Agency model.

At a bare minimum, for a reasonable sized manufacturer, they would require:

1. A suitably qualified QA Manager (in limited supply, even in Australia) who is willing to subject him (or her) self to the risk and liability associated with such a position
2. At least 2 to 3 suitably qualified analysts for Raw Material, In Process and Finished product QA work
3. A range of equipment necessary to analyse the types of Raw Materials and products that would pass through the facility (HPLC, HPTLC, Gas Chromatagraphs, UV Spectrophotometers etc.)
4. Suitably qualified operators to use such equipment
5. Validated Methods for all assays to be undertaken in the facility

The other option to items 3 and 4 above is to use the services of external laboratories, if they exist. This would serve to increase the cost and time necessary to release either or both raw materials or finished products.

The option used by many Australian manufacturers is to do some Analytical Work in-house and out-sourcing the remainder. Both methods are costly and in New Zealand, from our discussions, there appears to be little out-source capability or capacity available.

The only other option is to out-source all or much of these capabilities to an off-shore source. **This is neither desirable nor practical for the day to day operation of a business**, and is sending New Zealand businesses off-shore.

Release for Sale

All products require a formal Release For Sale process, usually done by the QA Manager. In the absence of an in-house QA Manager, the alternative is to find a suitably qualified Consultant who has TGA authority to release products for sale on behalf of a Sponsor or Manufacturer, at additional cost.

Raw Material Testing

The key to a quality product starts with the raw material that is used.

Raw Material testing is usually done by the QA Department in a manufacturer’s facility, or out-sourced to suitably qualified external laboratories. At present in New Zealand, neither of these options exist to the level necessary to meet the Joint Agency requirements.

In order to meet the Joint Agency requirements, Raw Material suppliers must supply appropriate documentation on the Raw Materials that they supply. This documentation can also be required during Supplier Audits, where the facilities, quality and capability of the supplier are also evaluated.

The testing requirements of the Joint Agency are, in my opinion, far too stringent, imposing significant and unjustifiable costs, given the Low Risk nature of the ingredients and products. A more reasonable testing programme would be adequate, and would typically include:

- Identity Testing
- Microbiological Testing for Botanicals
- Yeast and Mould for ingredients likely to be susceptible to these organisms
- Heavy Metals

For Low Risk products, this level of testing would probably be adequate without imposing unsustainable cost penalties.

In Hong Kong a few years ago, when a TGA style GMP ONLY system was introduced, the number of manufacturers dropped from over 60 to 10 or 15, **solely** due to compliance costs. That did not include all of the other aspects that the Joint Agency proposes

Sponsor Costs

Because of Australia's somewhat restrictive ingredient list, a large number of currently available ingredients would disappear (estimated to be up to 700). These "lost" ingredients would, obviously, lead to lost products in the local market.

The addition of new ingredients to the Australian Permitted List has been very slow. Relatively few have been added in the last 3 years. One has been pending for over 5 years (CLA), despite being widely available in New Zealand, the USA and Europe. Based on this adoption rate, it would take many, many years, using the TGA's current process, to replace anywhere near those 700 "lost" items. Even then, a number would probably never be added.

The cost to have a new ingredient evaluated is significant. While the evaluation may only cost in the region of $5,000 for a simple submission, the assembly of the dossier could cost $15,000 + depending on the ingredient. An indicative cost of having these "lost" ingredients added would be well in excess of A$14 million and would take years to return to the current position.

History has shown that whoever funds a new ingredient is little more than a benefactor to industry, because once an ingredient is approved, it is then freely available to any other manufacturer or sponsor to use. As such, there is no commercial incentive to invest, and without this investment, the industry slips further behind the rest of the developed world.

Under the Australian rules, all sponsors are expected to hold Stability data as the basis of the allocation of their Shelf Life claim. Stability would, potentially, become one of a

Sponsor's biggest costs. A Stability Programme on a single batch could cost between $5,000 and $25,000 per product for a 3 year programme –depending on the product, and new batches would need to be put down every year for a 3 year Programme, with a similar 3 year cost. In theory, a Stability Programme should include 3 batches per year of each product, thereby markedly increasing the cost to the Sponsor.

Two or 3 years ago, Marcus Blackmore, the Chairman of Blackmore's, one of Australia's largest natural products companies, commented that changes in TGA requirements have resulted in an increase of around A$2 million to his product cost, purely as a result of continual regulatory requirements, with no discernable change in the quality of his product.

Export Impact

As I have travelled extensively in Asia, I have seen many New Zealand products in numerous Asian markets. The Joint Agency proposal has the potential to significantly damage NZ Exports of CHP's through:

- Increased Compliance Cost = Loss of competitive advantage
- Significant delays in securing appropriate documentation
- Loss of Free Sale Certification currently available under the New Zealand system. Under the Joint Agency, many NZ products that are currently being exported, but did not fit the Joint Agency model, would no longer be acceptable in many countries as a result of the unavailability of appropriate Free Sale Certification. While an Export Certificate of Pharmaceutical Product (CPP) would be available that would allow for the legal export from New Zealand for products that are Licensed under the Joint Agency, this document is not considered a valid Free Sale Certificate in most export destinations, and as such, would not be acceptable for either the initial application or renewal. This would place the New Zealand Exporter at the same commercial disadvantage as the Australian Exporter.

The proposed Joint Agency provides for "… the timely availability of Therapeutic Goods …". The Australian model does not deliver on this commitment, certainly when applied to Export.

Risk Factors

All "Listable" products in Australia are considered Low Risk. In my view, the Compliance applied to them equates to High Risk. There is little difference in the Compliance requirements between Over the Counter (OTC) products and CHP's, despite a clear difference in their risk profile.

The comments by Annette King in "Focus on Politics" 23 March 2007 is a significant over simplification of reality. The implication is that if a product complies with the Australia list of approved ingredients, then the product would have automatic registration under the new system. This is partially correct. However, if an **ingredient** is not on the

Australian Approved List then they would have a very short life under the new Agency. Additionally, the product would also have to meet **all** of the additional criteria of the Joint Agency to survive. This would include a provision that the product must be **manufactured in an Agency Approved facility**. Many products currently available on the New Zealand market would not meet this element of the equation and consequently could be deemed ineligible to be marketed locally.

Options

Revisit the New Zealand Government Health Select Committee Report, December 2003.

In the same edition of "Focus on Politics" concern was mentioned that no-one would take a New Zealand only system seriously. The use of HACCP or an ISO Standard, or a combination of both, would be a step in the right direction, as both are globally recognised standards.

Summary

The Joint Agency equates to increased costs and restrictions for everyone;

- Manufacturers
- Sponsors
- Consumers

Do the benefits justify these significantly increased costs? It is hard to see an economic argument for it.

Given that Consumer Safety has not really been an issue, and there are not bodies in the street as a result of CHP's, it is difficult to justify the proposed model on safety grounds.

Perhaps as important for New Zealand, the proposed agency would threaten NZ Sovereignty with New Zealand products under the control and direction of an off-shore agency with NZ having limited input into the Policy or Rule determination of the agency.

In my view, the Joint Agency represents a retrograde step that costs much, delivers little and is potentially damaging to New Zealand industry and consumers.

Thank you for the opportunity to talk to you today.

John N. Thomas
Director
Registrasia (Hong Kong) Limited