Val Johanson Appendix to the Select Committee submission March 2007

Impact of TransTasman Harmonisation on the New Zealand Natural Healthcare Industry

The Australian Health and Wellness industry has been operating under the Therapeutic Goods legislation for fifteen years during which time the costs for small business have escalated and many small businesses have closed down. Ever increasing costs, increased regulation and time delays are resulting in products being taken off the market as companies rationalise their costs and product ranges. Agency registration fees are only a minor cost compared to the significant analytical and validation costs for these very low risk products.

Companies are using off-shore manufacturers, or moving their own operations off shore, and are having difficulty competing in the global market, adversely affecting our export. Costs and time delays are impeding innovation and consumers are understood to be importing greater quantities of natural products for their own personal use as products become too expensive or unavailable in Australia.

Establishment of a joint therapeutic regulatory agency between New Zealand and Australia under the currently proposed regulatory framework, will significantly raise compliance costs resulting in:

- **loss of low risk natural health and wellness products that New Zealand consumers are currently using to optimize their health and prevent disease**
- **increased price of remaining products**
- **closure of an estimated 50% of New Zealand businesses**
- **adverse impact on commercial Rongoa**
- **loss of jobs**
- **loss of tax dollars**
- **dramatic decrease in export as increased compliance costs for New Zealand products will render them commercially uncompetitive, and require registration in many export markets as medicines**
- **lost opportunity to lead the world in developing a world class regulatory model for low risk natural healthcare products**
- **a range of generic 'look alike' less complex products containing the same basic ingredients, instead of the innovative unique products that currently characterise the New Zealand market**
- **greater use of lower quality herbal ingredients and more generic, weaker claims**
- **loss of consumers' freedom of choice of a wide range of low risk natural health and wellness products**

Some groups in Maoridom are greatly concerned over the JTA proposal. The elimination of access to commercially produced Rongoa (traditional medicines) and the devaluation of all Maori Natural Health Product assets, will have a spin-off affecting future opportunities for improving general and economic health and wellbeing of Maori throughout the country.

New Zealand has the opportunity and potential to become a world leader in developing a sustainable health policy based on wellness, that encompasses an appropriate regulatory model for low risk natural health and wellness products. Such a model will optimise the health of New Zealand consumers, maximise the New Zealand Wellness brand and secure New Zealand's place in the global market resulting in a sustainable, innovative Health and Wellness industry and a lead economy.

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The challenge for government is to create an environment in which consumers can have freedom of choice of a wide range of quality, low risk natural health and wellness products that respects philosophical and cultural diversity, and good information to assist consumers take greater responsibility for their own health and wellness.

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1. Purpose

I have been requested by IM Health, New Zealand, to provide an expert opinion based on the Australian experience under the Therapeutic Goods legislation over the last 15 years, on the expected impact that Trans Tasman Harmonisation for therapeutic goods as it is currently proposed will have on the Natural Health and Wellness Products industry in New Zealand.

I fully support appropriate regulation of natural health and wellness products at a level that is commensurate with the low risk nature of these products, to ensure consumers have access to a wide range of low risk, high quality, efficacious goods, and that does not impact upon philosophical and cultural diversity. It is not appropriate to regulate very low risk products in a high risk pharmaceutical environment

2. Qualifications

In brief, my qualifications and expertise to provide this opinion are

- 12 years experience in food regulation
- 4 years as Head of Surveillance in the Therapeutic Goods Administration
- 9 years with the Australian peak body for natural health and wellness products, including seven years as Executive Director
- 7 years involvement in the negotiations of trans Tasman harmonisation
- 2 years facilitating Australian and New Zealand export

3. Background

Current health policy in Australia and New Zealand is premised on the treatment of disease rather than health optimisation. Healthcare delivery is focused on cure of disease or symptom relief. Prevention of disease and the overall wellbeing of consumers and the health system receive little attention – a disadvantage for the wellbeing of both consumers and the health system.

The escalating costs of healthcare in an ageing population are a critical issue for governments worldwide and require the adoption of healthcare policies that embrace natural healthcare, are based on a wellness system of health optimisation, the prevention of disease, and empower consumers to take greater responsibility for their health.

Consumers today are well informed and are increasingly choosing natural healthcare products to optimise their health and wellbeing. The New Zealand Ministry of Health's 1997 National Nutrition Survey revealed that 60% of New Zealanders consume natural healthcare products with nearly 50 percent consuming them on a daily basis. The market has grown significantly since then and it is estimated that about 70 percent now consume these products.

It is estimated that New Zealand consumers spend approximately $250million on natural health and wellness products per year.

There is a large body of evidence to support the efficacy and safety of natural health and wellness products, and the extremely low risk of these products is without question. There have been fewer than five disputed deaths in Australia due to complementary medicines in the past decade, clearly demonstrating the extremely low risks associated with these products.

Recent research has indicated that many of the ancient curatives used in Rongoa or Maori medicine have a valid scientific and pharmacological base. Commercial Rongoa is growing and has the potential to become a significant and valuable part of New Zealand's health and wellness industry.

The challenge for government is to create an environment in which consumers can have freedom of choice of a wide range of quality, low risk natural health and wellness products that respects philosophical and cultural

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diversity, and good information to assist consumers take greater responsibility for their own health and wellness.

New Zealand has the opportunity to become a world leader in developing a sustainable health policy based on wellness that encompasses an appropriate regulatory model for low risk natural health and wellness products. Such a model will maximise the New Zealand Wellness brand and secure New Zealand's place in the global market resulting in a sustainable, innovative Health and Wellness industry and a lead economy.

4. The Australian New Zealand Therapeutic Products Authority[1]

On 10 December 2003, the Australian and New Zealand Governments signed an agreement[2] to establish a joint regulatory scheme for therapeutic products, which will replace the Australian Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (Medsafe).

The proposed joint scheme would regulate medicines (including natural health and wellness products) and will come into force on the passage of legislation and ratification of the treaty.

5. The Trans Tasman Regulatory System in brief [3]

The regulatory system that is being proposed under a Joint Therapeutic Goods Agency between New Zealand and Australia would introduce regulation of natural health and wellness products under a pharmaceutical regime as currently exists in Australia.

In simple terms it would require:

- pharmaceutical manufacturing standards
- licensing of domestic manufacturers and audits of off shore manufacturers
- stability data, validation of methodology(both process and analytical), identification and authentication of ingredients, extensive testing of final product, levels of evidence to support claims etc
- use of permitted low risk ingredients
- registration of products for domestic supply, import and export
- approval of advertising
- post market monitoring
- evaluation of new ingredients prior to their use in commercial health and wellness products

All of these regulatory elements incur considerable and unnecessary cost.

It should be noted that the Therapeutic Goods Administration is currently undertaking a review of the policy framework for regulating products at the cosmetic/therapeutic interface. Outcomes of this review may impact on the regulation of these products in New Zealand under a Joint Agency.

5. Australian Experience under the Therapeutic Goods Act 1989 and Regulations

Anecdotal evidence confirms the closure of many small businesses when the Therapeutic Goods Act 1989 and Regulations were introduced in 1989, due to increased regulatory requirements and associated costs.

[1] www.anztpa.org/index.htm
[2] Text of Treaty between the Australian and New Zealand Governments www.anztpa.org/about/treatytext.pdf
[3] Consultation documents for the Australia New Zealand Therapeutic Products Authority www.anztpa.org/consult/consdocs1.htm

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Over the last 15 years, and especially since the Pan recall, regulatory requirements and scrutiny have increased dramatically with Blackmore's recently confirming an increase of $2million annually in compliance costs post the Pan recall- the biggest medicine recall in world history and still no evidence of serious harm arising from any natural health product manufactured by Pan Pharmaceuticals at that time.

Marcus Blackmore's position statement dated 29 June 2006, claims that *"In Australia, regulatory creep exacerbated by the recent Pan crisis has resulted in a drug-based model of over-regulation and unnecessary red tape that is too complex, too costly and bears little relativity to the level of public risk involved."*

The effect of these increased costs of compliance are resulting in:

- increased product prices to consumers
- rationalisation of product ranges with many products no longer available
- less products being registered with the TGA affecting their budget and resulting in increased fees and charges due to full cost recovery
- greater difficulty competing in the international market, with direct impact on our export
- increased numbers of companies going off shore
- difficulty for smaller companies finding manufacturers who will do small batch runs
- increased mail order for personal use
- stifled innovation
- lack of new products

5.1 Examples of Compliance Costs under TGA system.

5.1.1 Registration costs for listable product (low risk ingredients and claims)

Following a considerable shortfall in the TGA budget for 2004-2005, due largely to companies reducing the number of products listed because of exorbitant compliance costs, a 28% increase in product annual charge was introduced last year , raising the cost from $A540 to $A690 per product per year, and an increased application fee from A$500 to $520 per product.

More complex registrations are requiring greater use of consultants especially for smaller companies, with consultation costs of approx A$1000 per product. Searches for evidence to support claims and summaries of this evidence costs between $1000-2000 per product.

It is likely that more products will be cancelled and the situation will repeat itself next year with more increases necessary to meet the budget shortfall. These proposed increased costs have been delayed pending further consultation with the Australian industry.

Registerable products (higher risk and claims)

The TGA has introduced a 20% increase in all application fees to A$950, plus the annual product charge now A$880 per product per year. Evaluation fees for non prescription registered medicines were also increased by 20% to A$6320- 44200 depending on number of pages for evaluation.

Exemptions

To reduce the regulatory cost for products with very low circulation, exemptions can be sought (for a fee) from annual charges where the product annual charge exceeds 6.8% of the estimated or actual value of wholesale sales turnover of a product. This often applies during the first year of marketing a new product.

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Evaluation of new ingredients
Evaluation of submissions for new ingredients or for claims relating to cure or treatment or more serious diseases and conditions, are charged on a per page basis- (A$6320- 44200 depending on number of pages for evaluation and also recently increased by 20%.). Consultants fees are in addition to these charges.

5.1.2 Stability data
Indicative stability data cost for a multivitamin and mineral product containing selenium, folic acid, a range of vitamins and minerals, for a three year program with 9 testing stations over the three years, folic acid dissolution testing, restricted ingredient testing etc. could be A$20,000 for each batch put down.

For simpler products the stability costs could be expected at a minimum A$5000 for each batch.

Stability testing is an ongoing issue requiring additional batches to be put down for stability testing at regular intervals.

Some overseas countries are now regulating Australian natural products as medicines on the basis of the TGA approach. In these countries, stability data may be required for two or three batches for Australian made product.

5.1.3 Method Validation
In cases where a method in a monograph from an acceptable reference text may not be appropriate, alternative methods will need to be developed and validated at costs ranging from A$10,000 to A$15,000 per test method, depending on the complexity. Several tests may need to be developed for a complex product, each incurring costs of this magnitude.

These costs can be shared or amortised among other companies but the first company seeking the analytical work is often the one who pays up.

5.1.4 Herb Validation
In order to make a claim relating to level of standardisation of an ingredient in a natural healthcare product, quantification of the amount of a herbal component in the product is required.

For example, approx A$12,000 has been recently quoted for quantification of silymarin, but this may vary according to the herb, the complexity of the formulation, the dosage form matrix (tablet, SoftGel) etc. These costs are considerably higher for multiple herbal compounds in a combination product.

Most research is done on standardised extracts, providing good data to substantiate stronger and more meaningful claims, but use of the better quality and higher priced extracts (standardised) incur additional costs which are acting as a disincentive for innovation and the use of better ingredients and better claims.

5.1.5 Testing of Final Product
For the multivitamin example above, an indicative analytical cost for testing the finished product can be up to A$2,000 per batch. This includes testing of restricted ingredients, dissolution testing of folic acid and some micro-dose ingredients (selenium, copper etc.), tests for the metals and some vitamins

It should be noted that testing is time consuming as well as costly and impacts adversely on innovation, and development of new products.

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5.1.6 Cost of GMP audits[4]

Domestic audits

Hourly rate is $460 per hour per auditor plus travel and accommodation costs if applicable. Audits can range from 2 auditors for two days up to several auditors for a week or more depending on the operation. There have been some audits in Australia where up to five auditors have arrived unannounced and spent up to a week or more undertaking audits- this can result in costs ranging from $14,000 to over $85,000 per audit.

Overseas Manufacturer

The GMP Audit fee for an overseas manufacturer is A$940 per hour, plus Business Class airfares, plus four star hotel, plus per diem, plus TA. It is not unusual for 2-3 auditors to undertake an initial overseas audit which may take up to 2 weeks. Some audits have been quoted well over $100000.

5.1.7 Other manufacturing costs

Annual License fee is A$4450- $8630 including containers in which therapeutic goods are packed.

5.1.8 Advertising Approvals

Advertisements in main stream media including newspapers, magazines, radio and TV are required by law to be approved- for a fee.

Fees for advertisements in print media are currently A$160-A$330 depending on the number of words. Further time taken to negotiate an advertisement is charged on an hourly rate of $140 each additional hour or part thereof.

Fees for radio are A$310 and for 150 seconds on commercial TV are A$840.

It should be noted that under a Joint Agency it is proposed that advertising controls be extended to other advertising media such as recorded messages on business phones, and that all advertisements including point of sale material, letter box drops, shelf talkers etc. will require notification for a fee, incurring additional costs.

5.1.9 Sample Cost for Getting a Product to Market with a Claim for a Standardised Herb

These are indicative costs only and will depend on the complexity of the product and the claims made. Increases in fees and annual charges of up to 28% were introduced last year to meet the shortfall in the budget as more and more companies cancel products from the Register.

- **Product listing application** **A$520**
- **Levels of evidence** **A$1000**
- **Stability** **A$20000 – per batch program***
- **Methodology validation*** **A$15000 [shared cost]**
- **Herbal validation (silymarin)** **A$15000**
- **Finished product analysis** **A$2000**
- **Advertising approvals** **A$500 [average]**
- **Consultant's fees** **A$1000**

TOTAL **$55000** **(approx)**

[4] TGA Schedule of fees and charges- GMP www.tga.gov.au/docs/html/fees05.htm#gmp

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*** Note:** This cost can be shared among companies and may be considerably more for a complex multicomponent product containing several herbs, which will then require development and validation of several tests methods.

*** Stability is an ongoing program requiring a batch of product being put down each year for ongoing stability testing (potentially A$20000 per batch per product per year).**

5.1.10 Other Fees and Charges

- Annual charge A$690
- Evaluation of safety of goods A$5070
- Evaluation of new ingredients A$6320 (1-50pages) to A$44,200
- Certificate of CPP for export A$110 per product
- GMP Licence fee A$700

These costs are all new to New Zealand small business unless they are currently TGA compliant. .

5.2 Case Studies

Below are some case studies that have been reported over the last few years.

5.2.1 Small Australian company based in Queensland

- Came to Australia in 1991 to establish an agency for US products
- Incurred the following costs:
  - $80000 consultancy fees in 1992
  - >$20000 for each of four subsequent regulatory changes that required reformulation, new artwork and labels for each product
  - $60000 consultancy fees in 2004 from more legislative changes, PLUS $50000 in repackaging costs
- Manufacturing costs have increased by 300% since the Pan recall.
- In 1992, 95% of business was in Australia, but is now less than 5%
- Current internet business based in Auckland shipping to Australia is now bigger than the company's domestic Australian business
- Intend to close the Auckland office if the JTA comes into effect

5.2.2 Company with Offices now in Australia, NZ, USA, UK, EU, ME and SEAsia

- Company is familiar with the relevant regulatory requirements in these countries
- Middle East now requiring increased documentation and registration as medicines because of TGA regulation as medicines, incurring further costs and time delays
- This documentation is not required from countries that regulate under food law similar to NZ
- A NZ based client company with Australian made products is incurring an additional $14600 which would not have been incurred had the products been manufactured in NZ.

5.2.3 US Based Mail Order Business

- Mail order sales in Australia in excess of A$1million of non TGA listed complementary medicines which are imported legally for personal use- however it is illegal to sell same products domestically
- Cost of set up and compliance in Australia makes this a nonviable option.

5.2.4 Impact on Export

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- A Certificate of Pharmaceutical Product (CPP) application to TGA for shaped chewable vitamin tablets for export to Hong Kong
- TGA considered the shaped dosage form was an 'unacceptable presentation' and referred it to the regulators in HK for confirmation that it was acceptable
- Confirmation obtained, but was referred back by TGA to HK authorities to get approval for minerals as well as vitamins
- Approval took 8 months
- Similar process with the Indonesian authorities took 10 months for approval
- Delays such as this lose valuable export opportunities which often have a small window of opportunity which must be taken in a timely manner.
- Cost of compliance with TGA legislation results in Australian manufactured product being at least 150% more expensive in overseas markets than comparable US manufactured product, and therefore commercially uncompetitive

5.2.5 Manufacturing

- A quote from a non TGA approved manufacturer, with GMP and WHO recognition has quoted prices up to 75% cheaper resulting in serious consideration of moving off shore
- At least three of the medium to major companies in Australia are now either sourcing product from overseas or are in the process of establishing manufacturing facilities off shore to specifically avoid the TGA costs of compliance
- Three US companies with successful business in many parts of the world, view Australia as a non viable market because of costs of compliance
- It took two years for a company in India (which has FDA approval) to get a satisfactory response from the auditor, only to be told they were now due for another audit before the GMP Clearance Number could be given to them.

5.2.6 Solgar Australian Operation Closed Down

Solgar Vitamin and Herb, a Division of Wyeth Consumer HealthCare in the US, a leader in the natural products industry and the field of nutritional science, was established in the US in 1947, and is one of the industry's oldest and most respected researchers and manufacturers of premium nutritional supplements, distributing more than 450 quality nutritional products in over thirty countries around the world.

After six years attempting to operate in Australia under the TGA, Solgar has been unable to establish a viable business and has closed its Australian operation.

5.3 Offences and Penalties [5]

Finding senior Executives and experienced Quality Assurance Managers who are prepared to take the risk is becoming increasingly difficult following implementation of the new penalties and offences introduced earlier this year as the Therapeutic Goods Amendment Bill 2005.

Inter Alia, the Bill introduces draconian civil penalties for a low risk industry of jail sentences, or up to A$5.5million for a body corporate for importing or supplying therapeutic goods that do not conform with a standard applicable to the goods (new s14(1) of the Therapeutic Goods Act) .

It is pertinent that "A Guide to Framing Commonwealth Offences, Civil Penalties and Enforcement Powers" ("the Commonwealth Guide") issued in February 2004 by authority of the Minister for Justice and Customs,

[5] Therapeutic Goods Amendment Bill 2005- www.aph.gov.au/LIBRARY/pubs/BD/2005-06/06bd040.htm

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notes that the fine equivalent for life imprisonment is 2000 penalty units for an individual, and that the penalty for treason, certain war crimes such as genocide and certain terrorist acts is life imprisonment. The new s14(1) prescribes 4,000 penalty units, so importing low risk products that do not conform to an applicable standard carries twice the financial penalty as that for treason, terrorism and genocide.

It also introduces civil penalties, infringement notices up to $55000 for an individual and $550,000 for a body corporate for minor offences, extends the territorial jurisdiction of the Commonwealth to conduct by an Australian citizen or body corporate outside Australia and extends the liability of a body corporate to executive officers who are directly involved in the day-to-day management of the company, if the body corporate commits an offence or contravenes a civil penalty provision under the Act.

These new laws have been introduced despite TGA's proven existing ability to close down the largest manufacturer of complementary medicines in the Southern Hemisphere, despite no evidence of harm relating to a complementary medicine.

6. Expected Impact on the New Zealand Health and Wellness Industry.

In line with the Australian experience, it can be expected that establishment of the Australian New Zealand Therapeutic Products Authority, based on the Australian model, and the regulatory regime proposed for natural health and wellness products will be more severe than that experienced in Australia in 1991 as the regulatory requirements and cost of compliance have increased significantly over the past fifteen years. Very few, if any, ingredients were permitted between 1990 and 1998, and even after significant regulatory change, the system remains so onerous and costly that few new ingredients have been approved.

In summary it can be expected that :

- **Compliance costs for natural health and wellness products will escalate**
- **Over 50% of small businesses will close down or move off shore**
- **Jobs will be lost**
- **Tax dollars will be lost**
- **NZ export market will be severely impacted upon and be reduced dramatically**
- **Products will disappear from the market**
- **Cost of natural health and wellness products to consumers will significantly increase**
- **Consumers will lose their freedom of choice of a wide variety of low risk products for their own health and wellness**
- **Consumers will use mail order to import products of unknown quality, safety and efficacy for their own personal use**
- **Product innovation will be stifled**
- **New Zealand will lose its place in the global market as a leader in high quality, 'clean and green', innovative natural products**
- **Loss of commercially produced Rongoa opportunities (traditional medicines)**
- **NZ will lose the opportunity to develop a health system based on health and wellness with a risk based regulatory system that facilitates an innovative high quality natural health and wellness industry.**

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Tuesday, 4 February 2007

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