

Report of the Complementary Health Trade Mission to Asia 12- 24 November 2004

Executive Summary

Australia has one of the strictest regulatory systems in the world for dietary supplements. These products are regulated as medicines in Australia requiring pharmaceutical standards of manufacture and high compliance costs. Many other countries including US, New Zealand and many European countries regulate these products as supplements under food law without the need for pharmaceutical manufacturing standards.

The industry supports appropriate regulation as a means of providing consumer confidence in quality, safety and effectiveness. This tight regulatory approach combined with the clean, green, non polluted Australian environment resulted in international credibility for good quality product, and a growing export market valued at over \$200million per annum pre PAN.

The Pan Pharmaceutical recall in April 2003 was the largest medicine recall in world history, involving over 1600 products world wide. The very high profile negative media has damaged our international reputation resulting in US product that is not manufactured to pharmaceutical GMP and with little regulatory control, being the preferred product in Asia. Australian exporters have lost face, business and market share.

Australian domestic manufacturing capacity has stabilised, the domestic market is growing rapidly (over 15% pa). The export market is currently estimated to be well under half of the \$200million export market pre-PAN, and ongoing negative perception by Asian consumers is making it difficult to rebuild.

The objective of the two week Mission to Hong, Kong, Bangkok, Singapore and Kuala Lumpur was to address the negative perception by industry and regulators.

It succeeded in:

1. providing a forum to emphasise to the trade and the regulators, the strict Australian regulatory system which ensures that Australian made product is top quality,
2. facilitating positive meetings with potential trade partners,
3. facilitating constructive dialogue with regulatory officials in each of these countries,
4. confirming ongoing difficulties in re-establishing and growing our export market in complementary medicines (supplements), due to three main factors:
 - ongoing negativity by consumers about Australian made product,
 - high price Australian product resulting from cost of compliance under the TGA pharmaceutical regulatory regime being commercially uncompetitive, and
 - double standards being applied by Asian regulatory officials- less costly food standards for US supplements and costly pharmaceutical standards for Australian made product

Meetings with regulators were extremely constructive, providing updates of regulatory approaches in these countries, with suggestions for addressing the price disparity resulting from the highly regulated Australian system.

The assistance and support of Austrade both here in Australia and by those based within the region has been greatly appreciated, with the forums being professional and well attended. The Austrade brochure supporting the quality of Australian made product proved an excellent marketing tool. Graham Moulden's knowledge and expertise in the industry and the Asian culture and market was invaluable and greatly appreciated.

Initiatives have been identified for follow up in the near future to maximise the progress made during this event. Planning and programming for these events will be co-ordinated by Johanson and Associates, will require a national Austrade manager to liaise with the regional offices and need to be done well ahead of time to allow the maximum time for promotion and organising. The need for a follow up event in the short term was emphasised particularly in Singapore and Malaysia where the ongoing negativity appeared to be greatest.

These include:

1. **Public forums in Singapore and Kuala Lumpur with Austrade support around March 2005**
2. **Increased Australian presence at the NaturalHealth Fair in November 2005 with special seminars promoting Australian made quality and a possible half or full day to showcase the Australian industry**
3. **Austrade regional offices to organise Group buyers to the NaturalHealthFair**
4. **Package developed by Austrade on regulatory requirements within Asia**
5. **Options regarding addressing the difficulties in competing with a less costly, less regulated product coming from the US**
6. **Discussions between the TGA and the Malaysian regulators regarding special consideration of ARTG listed products under the PICS agreement**

1. Hong Kong NaturalHealth Fair – 10-12 November

Over 30 Australian companies exhibited at the Natural HealthFair organised in conjunction with the Cosmoprof Health and Beauty Show in Hong Kong from 10-12 November. Of these, fifteen combined under the Australian Pavilion, forming a strong Australian presence.

Although the focus of the Trade Show was Health and Beauty, the interest of the 30000-plus trade visitors included supplements and resulted in good numbers of visitors to the Australian stands with many positive contacts being made. These obviously require follow up on the part of the exhibitors.

Organisers of the Show expressed their interest through Michele Bernelli of Erboristeria (a co-organiser) to grow the natural supplement part of the show. They suggested a half day (or day) be dedicated to show casing the Australian industry, plus a much stronger seminar with powerful speakers focusing on quality, benefits, research etc. plus the opportunity to introduce and promote new products.

The Trade Commissioners suggested early planning and promotion with incentives to attract exhibitors, and that the regional offices could organise Group buyer delegations from each of the regions.

Interest and support of Austrade was greatly appreciated, with Sally Lam being very willing to attend to any and all issues, and both Michael Clifton (Sr Trade Commissioner) and Mark Wood (Trade Commissioner) attending daily. The Austrade brochure was an excellent marketing tool and very professional.

A debrief in the Wombat Bar following the close of the show caused some logistic difficulties with moving out but for those who were able to attend, provided a good opportunity to debrief. Michael offered to pursue the difficulties arising from cost disparity between the less regulated US products and the tightly regulated, high cost Australian products through DFAT if appropriate.

The logistics of move out following the show must be addressed for the next Fair.

Australian NaturalCare, Cardinal, Nutritioncare, Tabco, Phytomedicine, Sphere, VitalStrength and Johanson and Associates met with Mr Mak Yuk-Iun and Mr Yeung Yee-fai, Raphael of the Pharmaceuticals registration Section, Public Health Laboratory Section, Dept of Health Hong Kong and received an update on the registration process. Issues were raised regarding different standards applied for product coming in from HK (food standard GMP) versus Australian product (pharmaceutical GMP) and the competitive disadvantage from higher compliance costs. Five months for registration- details on website. Can seek advice on registration status from the department.



2. Bangkok Industry Showcase and Seminar and meeting with the Regulators- Nov 15-16

Great venue with professional presentation and display tables organised by Chutima of Austrade. About 30 industry representatives from over 20 companies demonstrated a keen interest in the presentations and products displays with good contacts. Thai industry showed a keen interest in sourcing raw materials, with several asking that next time we include raw material suppliers. Mr Ian Davey, Trade Commissioner opened the forum and accompanied the industry delegation to the



The issue of the Pan recall was raised with queries on what steps have been taken to ensure that another 'Pan' type disaster does not occur resulting in more hardship for Asian industry. The increased scrutiny and raised barriers by TGA were detailed.

Discussion with the Thai regulators (7) provided a good overview of current regulatory approach and proposed changes including the establishment of an Office of Comp Meds and the opportunity to seek clarification on the potential to supply product in competition with US product. Have a registration (6 mths) and a notification system - info on website. Stability requirements were outlined.



3 Singapore Industry Showcase and Seminar and meeting with the Regulators- Nov 17. Asian Nutritional and Dietary Supplement Conference on 18-19 Nov.

Good interest by over 40 industry representatives in a good venue. Strong messages and concern of ongoing negative consumer perception relating to Pan recall and the need to get positive messages directly to consumers. Janice Aw had produced an amazing outcome in very short time. Ms Maurine Chong, Senior Trade Commissioner opened the forum with an overview of the trade culture and opportunities of this international business hub.

The President and Secretary of the Health Supplement Association proposed a public forum with attention grabbing topics such as the killer diseases (heart attack, dementia, cancer, blood pressure, diabetes) in a few months time (March 2005)- strong Australian speakers, plus Singapore and TGA speakers. The need to organise in full consultation with Austrade, and promote early and widely with a public advertisement and through industry mailing and practitioner data bases was identified.



Questions about ensuring no future 'Pan' like disaster were again raised, with clarity being sought on current TGA action to ensure compliance.

Holding a public forum on the benefits and value of quality natural healthcare should attract sufficient critical mass to attract media interest and provide additional opportunities through media releases and interviews to get strong messages to the public.

An excellent meeting with Mr Chao Ye Peng, Head of the Health Supplements Unit in the Health Sciences Authority and Ms Christine Chay, Regulatory Scientist, confirmed the regulatory approach in Singapore which do not require registration in Singapore.

The Asian Nutritional and Dietary Supplement Conference was disappointing with less than 30 attendees including speakers, but presented another opportunity to emphasise the quality of Australian made goods.

4. Malaysia Industry Showcase and Seminar and meeting with the Regulators- Nov 22.

Good industry representation from Malaysia with around 50 participants. Opened by the new Trade Commissioner, Mr Tom Yates. Ongoing consumer negativity was again raised as a major problem with interest by PharmVision Ventures in providing assistance for a public forum similar to the one proposed for Singapore. PharmVision are also keen to use articles from Australia (e.g JCM or other experts) to help educate their consumers, and offering opportunities to test market new product through their magazine and pharmacy chains.

A very strong representation from the Malaysian National Pharmaceutical Control Bureau was present for the Seminar, lunch and three hour meeting (10 representatives including Director and 2 Deputies, Head of GMP, Supplement and Cosmetic Registration for the afternoon meeting). The regulators demonstrated considerable interest in the TGA system, raising the possibility that they may need to be more flexible in their approach and seeking information about the Australian list of acceptable ingredients.

On line registration system implemented in July 2002

The difficulty of competing against the lower price, less regulated US product was again raised, but despite considerable discussion and recognition of the problem, it was decided that there is no way under their law that they could grant a concession to TGA registered product. The Head of GMP suggested that as both Australia and Malaysia are PICs partners, we might take this issue up with the TGA and see if they would be willing to investigate the possibility of a fast track or special consideration with the NPCB.

Dinner with the Ag Trade Commissioner at his residence was greatly appreciated and provided an opportunity to debrief.

In summary

There is overall agreement that the mission was professional and very successful. Opening many leads which must be followed up to bring to fruition. The support and work of Austrade was greatly appreciated as was the presence of Graham Moulden travelling with us to give added advice on an as needs basis.

The [Austrade brochure](#) on '**Confidence for Asian Buyers- High Quality Australian Made Natural Health Products**' was a great marketing tool and has been well received both in Asian and back here in Australia.

There is unanimous agreement that this was a very valuable exercise and that we should work with Austrade to plan another similar forum next year, allowing more lead time to organise and promote to other industry members.