China FTA Taskforce
Department of Foreign Affairs and Trade
John McEwan Crescent
BARTON ACT 0221
Email: chinafta@dfat.gov.au

MEDICAL DEVICES INDUSTRY ACTION AGENDA (MDIAA)

Submission to the

Department of Foreign Affairs and Trade on the

Australia – China Free Trade Agreement

Dr Geoffrey Vaughan
Chair of MDIAA Strategic Industry Leaders' Group

Correspondence to:

Dr David Swanton
Manager
Medical Devices Industry Action Agenda
Level 9, 20 Allara Street
CANBERRA ACT 2601
GPO Box 9839
CANBERRA ACT 2601

1 July 2005

BACKGROUND

In April 2005, the Department of Foreign Affairs and Trade (DFAT) called for public submissions from individuals and groups on issues relevant to the negotiation of a free trade agreement (FTA) between Australia and China.

INTRODUCTION

As chair of the Strategic Industry Leaders' Group (SILG) for the Medical Devices Industry Action Agenda (MDIAA), I am pleased to submit this paper to DFAT on the Australia – China FTA in response to its call for submissions. This submission has been prepared in support of the Australian medical devices industry, however given the timeframe to develop this submission, the views presented here are preliminary in nature as they have yet to be considered by all SILG members. Once these matters have been considered by the SILG, we may wish to submit additional comments if appropriate.

MDIAA is an initiative of the Australian Government aimed at maximising the future growth and development of the medical device industry in Australia. Action Agendas seek to combine the expertise of industry and government to identify impediments to growth, harness competitive advantage and maximise opportunities for the development of industry sectors. Action Agendas are driven primarily by industry, with Government facilitating the process. Action Agendas are not about seeking government funding for industry. Information about the MDIAA can be found at www.industry.gov.au/mdiaa.

The current MDIAA vision for the Australian medical devices industry is:

> *'Unleash the innovative potential of the Australian medical devices industry through developing a vibrant medical devices technology industry by 2020, with more successful and growing companies and enhanced Australian and global health outcomes.'*

Although the MDIAA is in its development phase and strategic issues have yet to be finalised, it is possible to make some preliminary comments relevant to the FTA.

We are also aware that the Department of Health and Ageing has made a submission to DFAT, and that in 2000 the Therapeutics Goods Administration (TGA) signed a Memorandum of Understanding (MoU) with China on Therapeutic Goods (including medical devices). The MoU

covers an understanding of regulatory requirements and processes, development of professional competencies and development of a cooperative relationship.

WHAT IS THE AUSTRALIAN MEDICAL DEVICES INDUSTRY?

The *Therapeutics Goods Act 1989* defines a medical device as:

'any instrument, apparatus, appliance, material or other article, (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:

- diagnosis, prevention, monitoring, treatment or alleviation of the disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process; or
- control of conception,

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; or

- an accessory to such an instrument, apparatus, appliance, material or other article.'

Medical devices include a wide range of products such as medical gloves, bandages, syringes, condoms, contact lenses, X-ray equipment, heart-rate monitors, surgical lasers, pacemakers, dialysis equipment, baby incubators and heart valves.[1]

Demand and supply

Government is the industry's largest purchaser of medical products, with over 70 per cent of domestic sales made to the public sector. The remaining 30 per cent is sold to private hospitals, private practices, clinics, insurers and patients[2], although it may be the case that for many higher-technology products the bulk of sales are made to the private sector. Australia's medical devices industry would like to see the private sector drive the growth in sales of indigenous products and sales from Australian companies.

---

1 Therapeutic Goods Administration, Medical Devices – A New Approach to Regulation (May 2002).
2 IBISWorld Industry Report, *Medical and Surgical Equipment Manufacturing in Australia C2832* (2004).

Industry structure

Australia has a vibrant medical devices industry focused on exporting its products and creating overseas markets. The industry is serviced by two main industry organisations, AusBiotech (the biotechnology industry organisation) and the Medical Industry Association of Australia (MIAA), and also by two other organisations, Science Industry Australia and the Australian Electrical and Electronics Manufacturers' Association (AEEMA), all of whom are members of the SILG.

The Australian medical devices industry is largely comprised of SMEs, in particular, companies with fewer than 10 employees; and AusBiotech suggests that there may be a downstream employment multiple of approximately five for every one person directly employed in the industry**.** The top end of the industry is represented by its two truly global players: Cochlear and ResMed, both of which started from original Australian research, and much persistence by their founders. Brief profiles of these two large companies, and a smaller company, Portland Orthopaedics, are included at Appendix 1 to provide a profile of the types of companies that might benefit from an Australia – China FTA.

An accurate stock-take of the size and profile of the Australian medical devices industry is difficult in that companies captured by the TGA definition do not necessarily see themselves as part of the industry. This has resulted in differing figures for the size of the industry, ranging from 321 (Dr Lyndal Thorburn[3]) to 1 966 establishments (IBISWorld[4]).

Imports and exports

The industry is unique in that it imports most of what it uses (98.8 per cent), and exports most of what it produces (97.2 per cent), mainly to the USA, New Zealand, Europe, Japan and the UK. The global nature of the industry means that its future viability and continued success will be based on its ability to develop products for export markets. This raises the issue of whether an Australia – China FTA will offer opportunities for increasing exports to China. Import replacement, while desirable to build Australian industry, might not be possible unless new Australian products are based on globally competitive, leading-edge technologies that are more effectively marketed than products now marketed globally. Many Australian medical devices companies import products, including from China because either labour costs are much cheaper overseas, or the demand for some products might be supplied by manufacturers with a long-standing in the industry.

---

[3] BioIndustry Review Australia and New Zealand, 2005 Kelvin Hooper and Lyndal Thorburn

[4] IBISWorld Industry Report, *Medical and Surgical Equipment Manufacturing in Australia C2832* (2004)

MDIAA KEY ISSUES

For the medical devices industry, the most important issues relate to intellectual property (IP) protection and management, market access and regulation. Other issues for the medical devices industry in any FTA are non-tariff trade barriers, the elimination of which must be a priority.

Intellectual Property

IP management is probably the most significant issue for the medical devices industry, both domestically and in trade with countries such as China. As many Australian medical devices companies are small and medium-sized enterprises (SMEs), they will be particularly disadvantaged if their IP is not well protected or managed. Preliminary assessment indicates that it would be very difficult to protect the IP of Australian medical devices companies in a Chinese regulatory system.

This view is supported by comments by the chief executive of the Australian Chamber of Commerce and Industry (ACCI) Peter Hendy[5] that IP is one of the two biggest concerns for Australian businesses trading in China (the other is contract integrity). One specific concern in relation to the treatment of IP under any Australia – China FTA are the measures that companies can take under any FTA, and the costs, to address counterfeiting of medical devices products and components. The poor enforcement of IP rights in China is well documented and the protection of IP rights is critical to any trade negotiations with China.

Market Access

Another significant non-tariff trade barrier is the complexity of the distribution channels for products in China. Australian companies wishing to export medical devices to China and expecting sales to Chinese hospitals will need to understand the nature of, and be able to operate within, the Chinese regulatory and distribution systems, which may be quite complex. Customs regulations, constraints on the mobility of business people, and the complexity of access to government and private buyers of medical devices, could be a significant impediment to the ability of Australian medical devices companies to export products to China.

There is also concern about how Australian medical device companies, most of which are SMEs, can compete and collaborate with multinational companies in the Chinese market. Although some Australian medical devices companies already have established markets in China, an

---

5 Business Review Weekly (BRW), *Forward Thinking*, May 5-11, 2005

Australia – China FTA must facilitate more Australian companies gaining access to the Chinese market.

Regulation

The complexity and costs of Chinese regulatory procedures are a concern for some companies. An Australia – China FTA must not add to the complexity of commercialising and exporting products. It is important that the regulation of medical devices in China and Australia is both transparent and occurs in an internationally accredited manner. Technical regulations, standards and conformity requirements must not be burdensome. We agree with Rick Wells[6], chief negotiator for the FTA, who recently said that regulatory and behind the border issues have become more opaque and complex road-blocks to doing business in China.

On the other hand, Australia's regulatory framework, according to the TGA website[7], is based on 'a risk management approach designed to ensure public health and safety, while at the same time freeing industry from any unnecessary regulatory burden'. The new regulatory system for medical devices in Australia, which came into effect on 4 October 2002, puts Australia at the forefront of world's best practice for the regulation of medical devices. Australia has adopted the principles of the international regulatory model developed by the Global Harmonization Task Force, and it would be expected that China also adopt international best practice for its regulatory system.

Summary

An Australia – China FTA should provide economic benefits to the Australian medical devices industry by granting it access to a very large growing market. The Australian medical devices industry sees the need for developing stronger trade relations with China.

However, in addition to achieving greater market access and working within a harmonized regulatory framework, it is important that an Australia – China FTA includes measures to reduce non-tariff trade barriers, including helping safeguard the intellectual property of Australian medical device companies, improving market access and eliminating burdensome regulatory requirements.

Other issues related to an Australia – China FTA that will be considered by the MDIAA include market access in Australia for Chinese innovation, clinical trial opportunities for Australian

---

6 Rick Wells, quoted in The Australian, p. 23, 22 June 2005.

7 Therapeutic Goods Administration, Department of Health and Ageing, Canberra, 2005, viewed 23 March 2005 www.tga.gov.au.

companies in China, teaching and research collaborations between Australia and China, the development of reciprocal industry databases, and the identification of collaborative and cooperative opportunities.

Representatives from the SILG and I would be happy to meet with representatives from DFAT to discuss these issues, or to provide any additional information. I can be contacted directly at +61 3 5944 3457 or gv@bigpond.net.au, or preferably via Dr David Swanton on +61 2 6213 6480 or david.swanton@industry.gov.au

Dr Geoffrey Vaughan
Chair, Strategic Industry Leaders' Group
Medical Devices Industry Action Agenda

APPENDIX 1

Cochlear Limited

Cochlear Limited is just outside Australia's top 100 companies with a market capitalisation of over $1.5 billion. Cochlear has been one of the major success stories on the Australian share market over the last five years, experiencing enormous growth in revenue and operating profits and providing substantial share returns. Sales revenue for the year ending June was $282 million, below the record 2003 revenue of $306.1 million which reflects the impact of increased competition, pressure on clinics and a slower than expected uptake of neonatal screening and referral hindering forecast growth in the infant market. A large part of Cochlear's strategy is in supply chain management, which involves research collaborations with domestic partners to develop and supply key manufacturing components used in their products.

Cochlear develops implants which are a medical option for individuals with severe to profound sensorineural hearing loss in both ears.

China's low cost base may provide an opportunity for Australian medical device companies such as Cochlear to source components for their products. However, world-class quality management systems will be required to ensure that the Australian products maintain their global reputation.

ResMed

ResMed is a leading respiratory medical device manufacturer, specialising in products for the diagnosis and treatment of sleep disordered breathing. More than 95 per cent of all its products are exported to over 60 countries by employees and distributors with extensive knowledge and experience of local markets. This ensures that ResMed supplies the right products to the right markets—a key factor in the Company's business strategy.

Portland Orthopaedics

Portland Orthopaedics was established in 1991 as a group which included the University of the NSW Department of Engineering, Lucas Heights Atomic Research Centre and the CSIRO to research and develop the Margron Total Hip Replacement System. Portland Orthopaedics commenced exporting in its first three years of operation, and 80 per cent of revenue comes from exports. The view from within the company is that Chinese consumers demand foreign made medical products, and therefore China provides an export opportunity for Australian firms.

Over 1,500 patients have received the Margron Hip prosthesis and many more have benefited from an increased range of products, including, prosthetic components and instruments, all of which Portland manufacture to maintain complete control over quality assurance and supply.