

**MERCK SHARP & DOHME**

Marketing Our Innovations:  
How can we do it better?

***Improving the Pathways from Innovation to Commercialisation***

House of Representatives  
Standing Committee on Science and Innovation

Parliamentary Enquiry

**Submission by Merck Sharp & Dohme (Australia) Pty Limited (MSD)**

## **Executive Summary**

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The biotechnology sector has a leading role in Australia's efforts to achieve long term global competitiveness derived from a knowledge-based economy, based on Australia's strong science and education systems and the creative talents of its people. The quality of Australian bioscience and business management has not been matched historically by success in commercialisation.

Australian biotechnology's major successes are in the area of medical devices – the bionic ear (Cochlear Ltd) and respiratory support for sleep apnoea sufferers (ResMed Pty Ltd). Only one Australian designed pharmaceutical product has been introduced to the market – Relenza, a neuraminidase inhibitor for the treatment of influenza developed by Biota. In spite of this, the majority of Australian biotechnology companies are devoted to drug discovery<sup>1</sup>, mostly in basic science and preclinical phases.

Studies of Australian biotechnology have identified several points in the “science to product” sequence where improvements could sharpen the competitive position of the industry. These include improved levels of private sector investment and the formation of partnerships to move projects higher up the value chain and ultimately to commercialise the products.

This submission will focus on the role of international pharmaceutical companies as a source of scientific and business development resources, and as commercialisation partners for the local biotechnology industry.

## **Introduction**

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The market for pharmaceutical and biotech products is a global one, and having a global outlook is fundamental to any product, especially given the time-consuming, expensive and risky development paths. The innovation needs to be successful in multiple markets to justify and recoup the R&D investment.

The development path necessary to take any early stage pharmaceutical product through to market is incredibly long, complex and costly – far out of the reach of any small organisation to do alone. Success can only come from these small organisations forming partnerships with larger players. Alliances provide the researchers with access to funding, development capabilities, business management and marketing expertise necessary to enter international markets.

If the Australian local biotech industry is to deliver on its potential to be a significant contributor to Australia's future knowledge economy, then it must develop expertise and reputation in aspects of the biotech and pharmaceutical value chain – where it can be internationally competitive and attract international partners to fund their work and continue to develop the industry.

An international presence in the form of a strong, locally based pharmaceutical industry has much to offer the commercialisation process in terms of the business skills required during the development stages. These include clinical trials management, regulatory & reimbursement expertise, manufacturing skills, business

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1. Austrade web-site, biotechnology page, [www.austrade.gov.au](http://www.austrade.gov.au)

expertise in resource planning, financial & risk management and of course, marketing and sales.

### **Private Sector Investment is Critical**

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It is estimated that it costs approximately US\$802 million to bring a new drug to market (DiMasi, Hansen and Grabowski 2003). This is a significant amount of money, and the early stages of pre-clinical and clinical work especially encompass significant risk.

The Australian capital market alone is not large enough to support an Australian biotech company along this commercialisation path. Over the 4 years to 2002, most companies have managed to raise around \$AUS15 million in investment capital<sup>2</sup>, leaving a sizeable gap to be filled.

Global pharmaceutical companies such as MSD have the capacity to fund such work through to completion. In 1999, the local Australian pharmaceutical industry spent more than 10 times the amount of venture capital into medical R&D, investing \$AUS300m against a venture capital outlay of \$AUS25m. Global pharmaceutical companies are amongst the largest funders of R&D, with expenditure of \$US38.8bn in 2004<sup>3</sup>.

As mentioned earlier, only one Australian company has had experience of taking a pharmaceutical product from research and discovery phases through to market. Global research-based pharmaceutical companies have a long history in this exact area. They are part of the infrastructure that the government seeks to build.

### **Canada's Biotech Strategy**

It is illuminating to contrast Australian and Canadian performance in relation to successful commercialisation outcomes. Research undertaken by the Centre for Strategic Economic Studies at Victoria University of Technology (CSES) suggests that the biomedical industry in Canada is 3-4 times the size of Australia's, and is "more substantially integrated into the global biomedical industry than is simply explained by the relative size of the two countries".

CSES have considered a broad range of factors to measure comparative success. Many of these indicate areas of increasing variance between the two countries:

- In 2003, Canada had 3 times the number of patents issued than Australia (US Patent & Trademark Office)
- In their late-stage pipeline, Canada has 30 products in phase III clinical trials, and 60 in phase II, whilst Australia has 5 and 20 respectively (Ernst & Young Australian Biotechnology Report 2001, Rasmussen & Sweeny 2002)
- The total payout value of late-stage alliances between Canadian biotech and their clients was 37 times that of Australia (CSES)

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2. Centre for Strategic Economic Studies, Victoria University of Technology; Working Paper 8 2002  
3. Pharmaceutical Research & Manufacturers of America, PhRMA Annual Membership Survey 2005

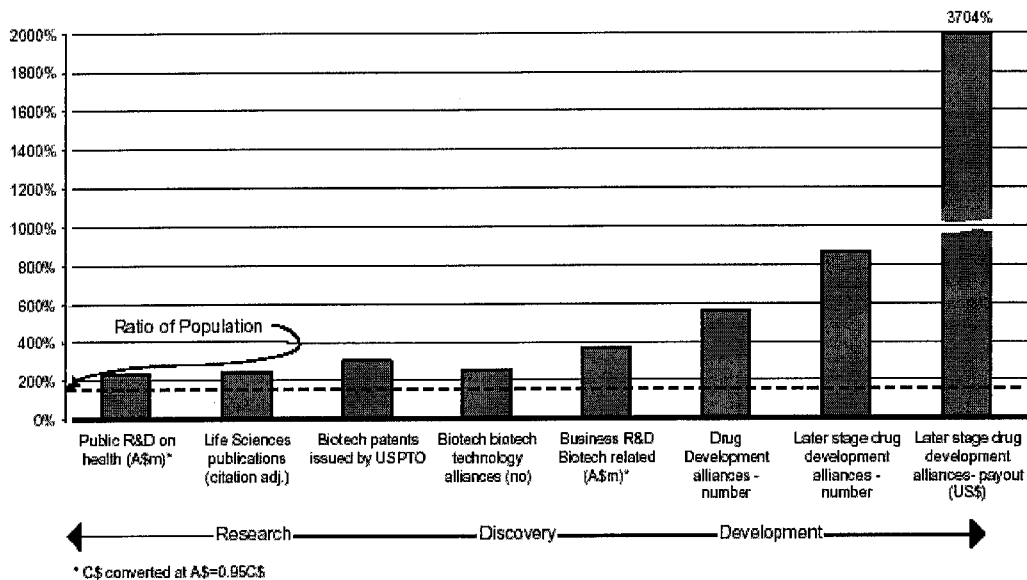
In considering the differences between Canada and Australia, CSES noted that:

- Canada's *public* sector investment in health R&D is nearly 3 times that of Australia
- Although both countries' *private* expenditure on health R&D has steadily increased over the years, Canada's rise has been noticeably steeper, especially over the last 4 years. Much of this has been achieved by implementing incentives for business

This would suggest that Canada has taken the right approach in committing public funding to enable early stage research and discovery, but has also ensured that this has been matched by private sector investment of sufficient scale.

The chart below illustrates the key factors used by CSES to measure progress of the biomedical sectors in the two countries. This clearly shows that the success being enjoyed by Canada increases exponentially in moving **along** the value chain towards commercialisation, with sizeable differences emerging at the later stages of development. From this data, it would seem that Canada has been able to achieve greater outcomes from its approach to commercialisation than has been achieved in Australia.

Chart 2. Ratio of Key Canadian to Australian Indicators for the Biomedical Sectors



Centre for Strategic Economic Studies, 2004

One of the noticeable aspects of Canada's biotech strategy is their emphasis and commitment to encouraging and enabling the global business community to invest in and partner with their local industry.

The implementation of strategies that ensure partnership investment at multiple stages along the path also helps build confidence and exit strategies for those investors. For instance, if there is confidence in the market that upon completion of a successful

discovery stage, a large pharmaceutical company would be receptive to investing in the development stage, then this provides confidence to the venture capitalists that they will have a buyer when they need to sell on their investment.

**There is a compelling argument that R&D investment by the global pharmaceutical industry, the largest and most closely strategically aligned source, should become a fundamental pillar of Australia's biotechnology plans.**

There are a number of barriers to increased private sector investment by the pharmaceutical industry in Australia. These include:

- An R&D tax concession regime which is essentially not able to be accessed by global pharmaceutical companies
- An operating environment which does not appropriately recognise or reward innovation

## **Partnerships**

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Business alliances and partnerships are now an established and vital feature of the international economy. This is particularly the case where the path to market for the product or service has characteristics that make it especially high risk, time consuming or costly – all three being key features of pharmaceutical and biotechnology developments.

The work undertaken by CSES concludes that alliances with significant global entities such as pharmaceutical companies represent the prime development path for Australia's biotech and research sector. In their comparative studies of Australian and Canadian success in commercialising biotech, they state that a critical part of Canada's success can be attributed to their ability to make their discoveries "attractive to a well funded pharmaceutical alliance".

The *Pharmaceutical Industry Action Agenda*<sup>4</sup> states conclusively that "strong links provide researchers and biomedical start-ups with access to experienced management, good advice and funding". Indeed, the document is subtitled "*Local Priority – Global Partner*". In its review of the common themes from the success stories, the document concludes that "common to all case studies was the importance of alliances or partnerships between participants along the pharmaceuticals industry value chain".

Most of the agreements MSD Australia has entered with Australian biotech companies have involved partnering on commercialisation experience and skills. This has been stated at the beginning as being a key need within the partnership, one which accelerates the company's development as a science-based business and provides a mechanism to gain knowledge and experience which would be impossible for them to access in any other way. Such agreements make for greater efficiency since each partner brings their essential capabilities to the business at hand.

It is vital that this process takes place so that the partnership can ensure that the discoveries are made as 'investment ready' as possible, to give them every chance of success. For example, Merck has had a 15-year history of partnering with AMRAD,

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4. Pharmaceuticals Industry Action Agenda, Local Priority – Global Partner; Australian Government Dept Industry Tourism & Resources, 2002

playing a vital role in its establishment by forming a joint venture. This has helped ensure that Australia has been able to build and develop some long-standing capabilities and experience in the area of biotech and pharmaceutical commercialisation.

The relationship has seen, and will continue to see, substantial investment by MSD/Merck to enable work to be conducted to increase the value of the Australian Intellectual Property (IP) and move it towards successful commercialisation.

In June 2003, MSD and AMRAD announced a significant research collaboration. Key aspects of which were the agreements around human capital. Merck brings to the collaboration strong skills in clinical development and marketing, which will enable AMRAD to accelerate the preclinical and clinical stages of the work. At US\$112 million plus royalties, this collaboration is arguably the largest biotechnology partnership in Australian history.

MSD has had a similarly long history of partnering with CSL. One of the fruits of this partnership – a vaccine for HPV – is one of the new major drugs in Merck's research pipeline.

#### **CSL's Partnership with Merck & Co.**

The discovery of the Human Papillomavirus (HPV) vaccine began in 1989 when a research group in CSL identified HPV as a potential vaccine target. The group joined forces with Professor Ian Frazer, now Director of the University of Queensland's Centre for Immunology and Cancer Research.

Professor Frazer's breakthrough came when he developed novel antigens that could be used as the basis for an HPV vaccine. CSL patented the vaccine in 1991 and selected Merck & Co., Inc. to license the vaccine in 1991. CSL had worked with Merck & Co., Inc. on other vaccine projects and was comfortable with the company's high ethical standards and strong capabilities in bringing products to market.

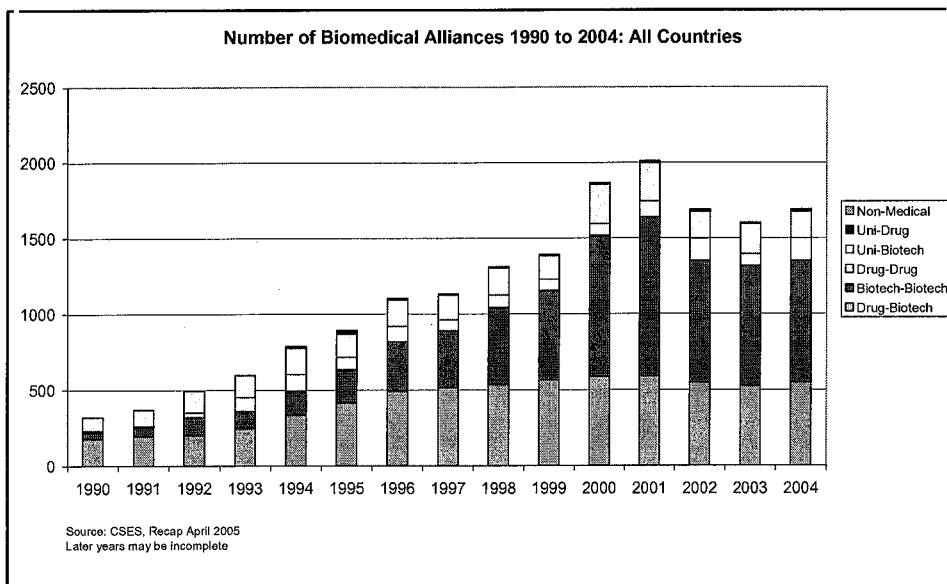
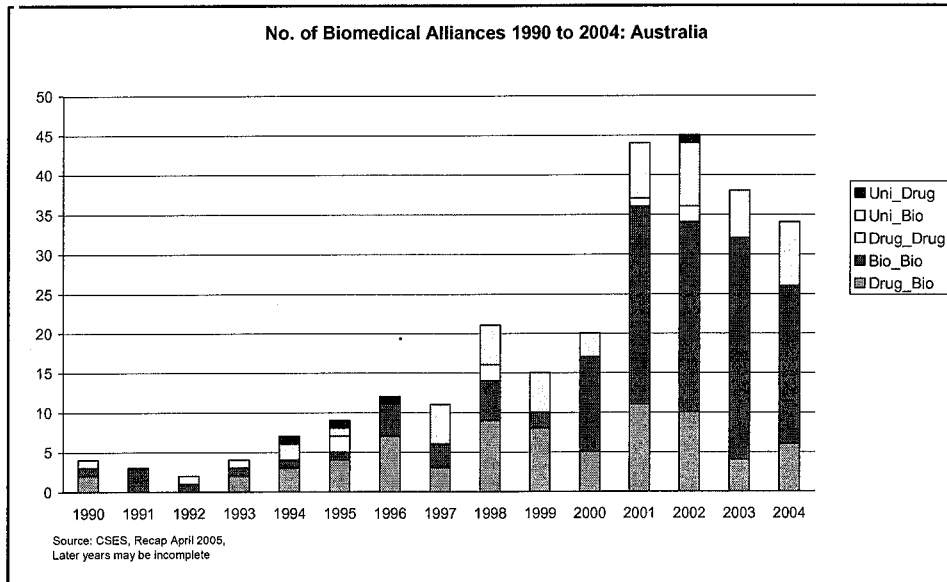
In 1995, Merck & Co., Inc. acquired exclusive rights to the technology and began a vaccine development program. By 1997, vaccine preparations suitable for clinical trial were available. Merck & Co., Inc. has taken the vaccine through Phases I and II clinical trial globally, first establishing the safety, biochemical and physiological effects of the vaccine on health volunteers and then focussing on efficacy and dosing regimens with small patient groups.

Merck Sharp & Dohme Australia is now involved in managing the Australian phase III clinical trial sites in Melbourne, Sydney and Perth

If it successfully comes through Phase III trials and fulfils its current promise, the HPV vaccine represents a significant advance in the prevention of cervical cancer globally. The four strains of the virus against which the vaccine affords protection, are associated with 70% of cases of cervical cancer. It has the potential to save 225,000 lives worldwide every year, and prevent almost half a million women from developing cervical cancer.

The HPV vaccine highlights the outstanding benefits to be reaped by collaboration between Australian researchers, local and global pharmaceutical companies.

Research conducted by CSES has shown that, although the number of alliances in Australia has grown dramatically over the last few years, the majority of these are between biotech companies, or between biotech and academia. These relationships are naturally focused on the transfer of technology within the discovery stages. The number of alliances between pharmaceutical companies and biotech, which is critical to successful commercialisation, remains relatively low.



It is MSD's contention that partnerships between local Australian Biotech and global pharmaceutical companies who have a strong local presence, are one of the key mechanisms for realising the huge potential of this emerging and highly valued sector.

### The Role of a Strong Local Subsidiary

Within a global company such as Merck & Co., decisions on whether to invest are largely based upon cost and comparisons with other competitive opportunities. While the quality of the scientific material will be paramount, the business environment

often becomes a tie-breaker between two closely evaluated prospects. A subsidiary with more resources available will be better positioned to evaluate and invest in new local innovations.

Advocacy within a global pharmaceutical company by a strong local subsidiary will increase investment attractiveness for a country's biotechnology offerings. A company like Merck & Co., will look at approximately 7,000 research proposals from biotechnology companies each year, and entered 54 license agreements in 2004. The sheer volume of applications means that only the best or the best presented ideas will gain notice. It is crucial to have a local presence championing Australian biotech to the company's head office – connecting the proposal to the right people, ensuring the innovation is clearly linked to the company's strategic areas of interest and expertise and smoothing the progress of the discussions.

For a strong local subsidiary to exist, the operating environment must be positive, allowing industry to grow and flourish. Programs such as factor f, PIIP and the current P3 play an important role in the growth of private sector R&D in Australia, as they redress some of the difficulties which companies face in the regulatory and reimbursement environment.

The local subsidiary can also play a key role in overcoming the perception that Australia is both small and located too far away. This problem has historically plagued Australian business looking to expand abroad, and the biotech industry is no different in struggling to overcome this perception in its search for investment. Canada has shown it is possible to overcome the barrier of distance, acting as it does as a 'developer' to such a significant number of European 'clients'.

## **Concluding Remarks**

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The basis for this inquiry is that innovation is a critical aspect to Australia's future economic health. A flourishing and globally competitive Australian biotechnology industry is fundamental to any knowledge-based economy.

MSD believes that partnerships between the local biotech industry and global pharmaceutical partners are the most effective key to achieving the successful commercialisation of Australian ideas.

Private sector R&D investment of sufficient scale together with access to business and commercialisation expertise are continually cited as the two major enablers to progressing discoveries along the value chain and getting a product to the worldwide market.

Global pharmaceutical companies are already significant funders of R&D, and unarguably are the most closely strategically aligned and committed sources of investment.

Australian government strategy must stimulate the formation of these partnerships by ensuring an R&D tax concession regime which can be accessed by global pharmaceutical companies and by having an operating environment which appropriately recognises and rewards innovation.