September 13, 2002

The Inquiry Secretary,
House of Representatives Standing Committee on Science and Innovation
R1 Suite 116
Parliament House
CANBERRA ACT 2600
Email: scin.reps@aph.gov.au

Dear Sir/Madam,

INQUIRY INTO BUSINESS COMMITMENT TO RESEARCH AND DEVELOPMENT IN AUSTRALIA

Please find attached a submission from Merck, Sharp & Dohme (Australia) Pty Ltd (MSDA) to the above inquiry.

MSDA is happy for its submission to be made public and would welcome the opportunity to address Committee members.

Should you have any inquiries regarding our submission, please contact our Principal Policy Advisor, Ms Sara Pantzer on 02-9795 9528, in the first instance.

Yours sincerely,

WILL DELAAT
Managing Director

SUBMISSION FROM MERCK SHARP & DOHME (AUSTRALIA) PTY LTD (MSD) TO THE STANDING COMMITTEE ON SCIENCE AND INNOVATION'S INQUIRY INTO BUSINESS COMMITMENT TO RESEARCH AND DEVELOPMENT IN AUSTRALIA

Background on Merck Sharp & Dohme (Australia) Pty Ltd (MSD) and its parent company, Merck & Co, Inc.:

MSD is the Australian subsidiary of US pharmaceutical company, Merck, and is celebrating its 50th year in Australia this year.

The company employs 850 staff and produces medicines for heart disease, high blood pressure, osteoporosis, osteoarthritis, asthma, Parkinson's disease, HIV/AIDS, glaucoma and vaccines for childhood diseases including measles and rubella.

MSD is a significant manufacturer with a state of the art manufacturing facility based at Granville in western Sydney. We supply markets in Europe, Asia and the Americas, making us the country's largest exporter of prescription medicines.

Research and development is one of the most important activities for the organisation and MSD is one of Australia's top 50 firms in this area. Each year, the company spends around $8million on Australian R&D from clinical trials to untied grants to research fellowships to licensing agreements. The company is currently involved in 56 clinical trials in 140 centres around Australia, treating more than 1000 patients.

Through its participation in the Federal Government's Factor F program, from 1988 to 1999, MSD made significant investments with AMRAD, CSL, the Garvan Institute and the University of Queensland. It also formed an $11 million partnership with the Commonwealth Government and academia to study hypertension in 6,000 elderly patients, aimed at identifying optimal hypertension management. The results of this landmark study were released earlier this year and are expected to transform the way high blood pressure is treated globally.

MSD's involvement with CSL has produced a candidate for a vaccine for human papilloma virus. The four strains of the virus against which the vaccine affords protection are associated with 70% of cases of cervical cancer. This candidate is one of the most promising compounds in the global company's pipeline.

For its parent company, Merck & Co., one of the key operating priorities is based on innovation.

The company recognises that the way to drive sustainable revenue growth in the pharmaceutical industry and to maximize sales growth is through its ability to innovate – to discover and develop medicines that save or improve people's lives.

The company's success depends on turning cutting edge science into breakthrough medicines. As a result, Merck is committed to increasing its emphasis on expanding our lead in cutting-edge science . This is the most productive time ever for Merck. We have launched 16 new medicines in the past 6 years and have more new research programs in early development than ever before in the company's history.

Along with the rest of the industry, the Merck budget for internal research has increased significantly from $US1.3 billion in 1995 to $US2.8 billion in 2001. While the company's laboratories are responsible for a substantial proportion of worldwide biomedical research output (between 1.5% and 2% of all published data) Merck recognises that external alliances are critically important to gain access to the other 98%.

Historically, 20-30% of Merck's sales have come from externally licensed products. Partnering and the company's ability to collaborate with the best R&D organisations outside of Merck will support its growth into the future.

Given the growing importance of the external licensing function, MSDA has established a new biotechnology R&D unit , headed by Professor Graham Macdonald. It is intended to work with the Australian R&D community to identify potential new compounds. This represents a major opportunity for Australian science.

Introduction

In a complex global industry such as pharmaceuticals, successful innovation is dependent on strong relationships between global corporations like MSDA and smaller R&D-focussed companies. To this extent, the presence and activity of global corporations in Australian R&D is critical if small and medium sized Australian companies are to reach their full potential.

With this in mind, MSD's submission discusses:
1. the benefits that flow from our participation in the Australian economy;
2. the impediments we face and
3. the factors which influence the extent of our involvement in Australian R&D.

1. The benefits from greater private sector investment in pharmaceutical R&D in Australia

There is immense value to be realised in forging a closer relationship between the Australian research community and pharmaceutical companies. By matching Australia's excellence in science with the industry's experience in getting products to market, the basis for a sustainable biotech sector can be established.

A strong locally based pharmaceutical industry is critical if the full potential of the local biotech industry is to be realised. The local industry spends more than 10 times what venture capital injects into medical R&D (industry spends $300m p.a.; Venture capital spent $25m in 1999).

A strong locally based pharmaceutical industry has much to offer to local biotech companies in terms of commercialisation, regulatory and marketing, manufacturing expertise and the development of human capital. The resulting strengthening of local pharmaceutical industry employment opportunities would also help stem the brain drain by providing skills development, access to a global science community and opportunities for career advancement etc.

It can be argued that the credibility gained on financial markets from successful global commercialisation of even one locally developed pharmaceutical agent would disproportionately accelerate the maturing of our biotechnology sector and its investment attractiveness, and the development of an indigenous Australian pharmaceutical industry.

2. Impediments to business investment in R&D

(a) The major impediment which constrains MSD's ability to increase investment in R&D is the **pricing and reimbursement environment.**

The prices which we receive for our medicines are amongst the lowest in the developed world and fail to recognise the considerable R&D investment made. Some of our medicines are not able to be listed on the PBS because the low price offered would have a flow-on effect globally.

If we cannot get a product listed, there is no real incentive to run clinical trials here. This was our experience with a product called COZAAR. COZAAR was the first in a new class of medicines to treat high blood pressure.

The combined effect of the PBS process and price outcomes result in reduced local revenue and an inability to predict forecast growth with any confidence. This means we are not in a strong position to lobby our parent company for further R&D investment as we are unable to be confident about the return on that investment. Our investment in human resources, IT, and other aspects of our domestic operation is also unstable.

The critical importance of the pricing and reimbursement environment for increased R&D was highlighted in a survey of head offices which was conducted as part of the consultation process for the Pharmaceuticals Industry Action Agenda (available on the Department of Industry,Tourism and Resources website).

The survey of multi-national companies aimed to gain a better understanding of how their head offices view Australia in terms of investment, to establish the key factors that are relevant for international investment decisions and how Australia scored against these factors.

The key conclusions from the survey were as follows:

In terms of R&D, pricing and reimbursement issues were ranked as the most important factors influencing decisions to invest. Regulatory issues were also ranked very highly while operational costs, taxation incentives and human resource and infrastructure were high.

Australia rated highly in terms of human resources, quality of skilled personnel and trial quality and Good Clinical practice (GCP) compliance and the rigour of its IP law.

However in the area ranked as most important for decisions to invest, that is pricing/reimbursement, Australia was considered poor. This negative perception applies to both the level of domestic pricing and the transparency and predictability of the process. Australia was also ranked poorly in terms of the taxation environment and incentives.

In terms of its investment attractiveness to the pharmaceutical sector, Australia ranks behind the US, UK, Europe and Singapore, bettering only New Zealand.

The survey and the perceptions of Australia as an investment location underpin a number of the key actions recommended through the Action Agenda – the critical importance of a new industry development program, the importance of partnerships, and the pivotal role for a comprehensive international marketing strategy in creating a more favourable positioning for Australia in the minds of overseas companies and investors. The Action Agenda is presently before the Government for consideration by Cabinet.

(b) The **taxation treatment of Research & Development expenditure** for pharmaceutical companies in Australia is a disincentive to investment in R & D facilities and activity. During the Factor (f) years the criteria for claiming R & D expenditure, for both Factor (f) and tax deductibility purposes, were that:

i. The R & D expenditure was made on appropriate, worthwhile projects that did/would lead to, in most cases, pharmaceutical products coming to market;
ii. The expenditure led to the exploitation of the product in and to the benefit of the Australian economy.

However during the 1990s the Australian Taxation Office (ATO) began to require and enforce a third criteria for tax deductibility and for the higher concessional level (originally 150%, reduced to 125% in 1996, an additional, premium rate of 175% introduced in January 2001) which was that:

iii. The intellectual property (IP) must be owned in Australia.

With the continual tightening of the application of this third criteria and, as a result of a number of ATO and pharmaceutical company agreements, the tax deductibility of R & D for most pharmaceutical companies in Australia has ceased.

This current situation is not conducive for Head Offices to look favourably upon Australia when decisions about investment in R & D are made, usually based on the most advantageous current or future tax environment.

3. What would make a company like Merck place R&D investment in Australia?

Pharmaceutical industry support for Australian biotechnology involves investment during the high risk phases of pre-clinical drug development - molecular design, biological screening, chemical characterisation and proof of concept. While we will invest wherever there is good, cutting edge science, it is the overall operating environment which would determine the extent of this investment.

An environment which is supportive of innovation and respectful of intellectual property would attract significant R&D funding from Merck. This is evidenced by our substantial R&D presence in the UK, Canada and Italy.

One of the markers of an environment which is supportive of innovation is the extent of government support for basic biomedical research. In the U.K. for example, the quality of the science base and the relevance of the long-term basic research carried out by universities, research institutes and medical schools have been key factors in attracting and maintaining a strong industry presence. The strong science base is the reason Merck decided in 1985 to locate its neuroscience research centre outside London in Harlow, Essex.

The costs of high quality research are significantly lower in Australia. This advantage is only partly accounted for by the currency exchange rates. The

quality of Australia's universities' undergraduate and postgraduate programmes is recognised as being world class. Australian doctoral graduates are highly competitive applicants for research and development positions worldwide.

A second important factor is effective intellectual property protection. Strong patent laws are important to research-based companies like Merck because they give us a chance to recover our investments in R&D, and give shareholders a chance to realize gains on their investments.

Australia enjoys world-class patent protection laws, and it will be important to remain competitive with the US in this arena. However, while the intellectual property regime is strong, its impact is undermined by the processes involved in pricing and reimbursement which do not respect innovation (see earlier, under Impediments)

The third factor is around clusters of innovation, sites of excellence. These have been of primary importance in the synergies between government, the academic community and the private sector in the US. Clusters like the Silicon Valley, the Route 128 corridor , the Research Triangle and San Diego, that dot the American landscape, have created a positive environment for innovation.

The fourth factor necessary for pharmaceutical innovation is a responsive regulatory system both at the level of clinical trial activity and drug registration. There have been real improvements to both of these processes in Australia over the past decade and the regulatory authority, the Therapeutic Goods Administration has a good reputation and delivers an efficient, transparent service. Registration times for new products lag slightly behind comparable countries like the UK. The challenge for the TGA is to remain competitive with other regulatory agencies, particularly given the actions by some Asia Pacific countries such as Taiwan and Singapore in this area.

Concluding remarks

It is MSD's contention that increased private investment in the pharmaceutical and biotech sector is dependent on relationships between small domestic research companies and global corporations. The potential for these relationships to develop will be determined by Australia having an operating environment that is conducive to innovation through effective IP protection and a competitive return on investment.