GlaxoSmithKline Submission to the House of Representatives' Standing Committee on Science and Innovation

"Inquiry into Business Commitment to Research and Development in Australia"

Introduction

Due to our extensive investment in Australian R&D and our desire and commitment to increase this, GSK welcomes the opportunity to provide a submission to the House of Representatives Science and Innovation Standing Committee and to assist in its Inquiry into Business Commitment to Research and Development in Australia. We would welcome any further opportunities to be involved in the activities of the Inquiry and to provide additional information or testimony as appropriate.

As a multinational company, GSK particularly welcomes the opportunity to comment on the considerations by which companies such as ours determine where to locate R&D investment and how Australia can reap the highest possible benefit by understanding and leveraging these drivers.

The economic benefit that could be gleaned through enhanced pharmaceutical investment is substantial and could result in Australia becoming a niche provider of services both to the region and to the global market. The environment that has created these opportunities will not remain static and steps must be taken now in order to achieve that position.

Background

GlaxoSmithKline (GSK) is a world leading, research-based pharmaceutical company with a powerful combination of skills and resources to meet the healthcare needs of people around the world, helping them do more, feel better and live longer.

GSK is a global leader in the research, development, manufacturing and supply of prescription medicines, vaccines, over the counter medicines, oral care products and nutritional healthcare drinks.

At the forefront of the rapid progress in science and technology that will transform medical practice over the next 20 years, GSK is committed to sustain its current R&D intensity and investment. GSK's global R&D budget is approximately £2.5 billion (A$6.9 billion) annually.

As a research based company, GSK has a significant R&D product pipeline, with many new chemical entities (NCEs) and vaccines in clinical development.

Our corporate headquarters is in the UK; we operate in more than 100 countries and employ over 100,000 people worldwide.

GSK Australia is a major contributor to the health and economic wellbeing of all Australians. It has two operating groups - GSK Australia Pharmaceuticals and GSK

Australia Consumer Healthcare. GSK Australia Pharmaceuticals head office is in Victoria, manufacturing and supplying prescription pharmaceuticals and vaccines to Australia and export markets. GSK Australia Consumer Healthcare headquarters is in New South Wales, manufacturing and supplying OTC medicines, oral care products and nutritional beverages to Australia and export markets. This submission is being made on behalf of GSK Australia Pharmaceuticals.

GSK employs approximately 1500 staff and its contribution to Australia's export revenue through pharmaceutical and consumer healthcare exports totalled $197 million in 2001. Our manufacturing operations perform a key role as a global supplier of medicines, exporting 50% of pharmaceutical production to 65 countries throughout Europe, Canada, South America, Africa, Asia, the Middle East and the Pacific Region.

GSK's prescription medicines, vaccines and consumer healthcare products help treat and prevent disease in millions of Australians and our product portfolio and focus is closely aligned with the challenges highlighted by the Australian Government. GSK Australia produces products closely associated with the National Health Priorities - asthma, immunisation, depression, diabetes and smoking cessation.

In addition to this, GSK's investment in research and development in Australia is over $25 million per annum and the company is ranked in the top 20 industrial contributors to R&D.[1] This investment bears testimony, not only to the quality of Australian science, but to the company's commitment to supporting the advancement of Australian R&D excellence.

Furthermore, GSK is involved in a whole range of R&D activities. We currently support more than 20 R&D discovery projects and approximately 80 clinical trials are on-going at any one time.

The discovery research collaborations cover a broad range of areas and include the increasingly important area of genetic research. Some of the areas covered by our discovery research collaboration include alzheimer's disease, cardiovascular disease, diabetes, hepatitis B, immunology, migraine, metabolic pharmacology, respiratory medicine and rheumatology.

GSK is also a major participant in phase 1 studies and international multi-centre phase II, III and IV clinical trials. The company's clinical trials involve clinicians and research centres around Australia in areas such as infection control, depression, cardiovascular disease, diabetes, cancer, asthma, rheumatology and tropical diseases.

One of our major research investments is the James Lance GlaxoSmithKline Medicines Research Unit at the Prince of Wales Hospital in Sydney. This unit, one of only five facilities supported by GSK worldwide, carries out phase 1 clinical trials, a crucial step in developing effective new medicines.

GSK Australia's research partnership successes have placed Australia on the global R&D map primarily through the discovery and development of *Relenza*™, the breakthrough treatment for influenza and *Kapanol*™, a sustained release morphine product for moderate to severe pain.

[1] R&D and Intellectual Property Scoreboard 2001

Drivers of Pharmaceutical Investment

The drivers of pharmaceutical investment have been extensively researched and debated by several countries, including Australia through the current Pharmaceuticals Industry Action Agenda – a draft of which is available at http://www.industry.gov.au

The United Kingdom has also recently investigated these drivers as part of the Pharmaceutical Industry Competitiveness Task Force (PICTF) established in March 2000. Like the Action Agenda process, the Task Force was designed to bring together the expertise and experience of industry leaders in order to determine the steps needed in order to retain and strengthen the competitiveness of the domestic business environment for the innovative pharmaceutical industry.

GlaxoSmithKline participated actively in both the Action Agenda and PICTF and believes that there is a high level of agreement across the two reports regarding drivers for pharmaceutical investment.[2]

These include:

- The condition of the local market
- Appropriate recognition of Intellectual Property rights
- Regulation of Medicines Licensing
- Science Base and Biopharmaceuticals
- Clinical Research
- Wider Economic Climate

Local Market Conditions

Key features of the local market are vital in the generation of R&D and the attraction of investment. These include factors such as access to market; efficiency of the registration system, pricing and reimbursement procedures; post marketing influences and practices; and the role and perception of pharmacoeconomics in influencing doctors' prescribing behaviour.

Where the industry cannot access the market for its products, it is highly unlikely to support other than the most necessary R&D in that environment. Equally, where registration, pricing and reimbursement processes are lacking in transparency and accountability, additional investment resources will not be forthcoming.

Considering that a significant percentage of global biomedical and biotechnology innovation is brought to market by the pharmaceutical industry, a healthy operating environment should be encouraged. A strong, viable domestic pharmaceutical industry, as supported by the National Medicines Policy, will increase the visibility of Australian biotechnology and the likelihood of critical partnerships occurring. The value to Australian research would then be realised with meaningful economic benefits ensuing.

Appropriate Recognition of Intellectual Property Rights

Effective intellectual property rights are essential to the continued flow of innovative medicines. Many of these issues are developing at an international rather than a national level but equally national governments have a strong role to play in the protection of these rights.

[2] Pharmaceutical Industry Effectiveness Task Force, *Final Report – March 2001*

Intellectual property is at the heart of the innovation conducted by the pharmaceutical industry. Without protection of the knowledge and innovation which supports our products, the industry's drive to develop and research new medicines is undermined. The outcome of this would be cessation of research and development and an inability to produce new innovative medicines for otherwise untreated diseases.

Regulation of Medicines Licensing
Regulatory systems impact strongly on international competitiveness. The submission of data, the exclusivity of that data and the capacity to engage in pre-submission dialogue regarding the submission is key in providing a predictable regulatory decision making process.

Globally competitive approval times for medicines and the possibility of more rapid availability of innovative medicines to patients are all key signals of the effectiveness and competitiveness of a regulatory body.

Science Base and Biopharmaceuticals
Having a foundation of sound science coupled with a strong skills base in employment produces an environment where the prerequisites exist for attracting innovation, research and development.

To become a highly favoured R&D site and attract high levels of investment, domestic education standards need to be world class and this needs to translate to strong links between industry and academia and good manufacturing science as well as a robust research capacity.

Clinical Research
Clinical trials are essential to the development of beneficial treatments for patients and consumers of medicines and healthcare. Clinical trials supported by the pharmaceutical industry strongly impact a country's ability to remain at the forefront of modern treatments and research.

Three main parameters identified in deciding where to undertake clinical studies include speed, in terms of start up times of clinical research; cost; and the quality of research.

Economic Climate
The Australian Government has long had as one of its key objectives the importance of making Australia a good place to do business by creating a stable and competitive economic environment. Many aspects of an economic climate can foster or constrain the competitiveness of the innovative pharmaceutical industry.

Some of these aspects include sound economic growth, stable inflation and low and stable interest rates. In addition, an open and outward looking market, with strong linkages to the rest of the world can be of great benefit.

Subject to the availability of the necessary science base, financial considerations will also influence decisions on the siting of R&D. Continued fiscal support for R&D allowances and tax concessions, along with reward for innovative practices, help maintain the continuance of international competitiveness.

The above indicators provide a benchmark against which to consider Australia's competitiveness in attracting investment in R&D. In addition, they also provide a

backdrop against which to consider what could be done to attract additional resources to Australia and what impediments exist to this.

Economic Benefit

Before assessing what policy measures may be needed to attract greater R&D investment to Australia, the economic benefit engendered by the current activities of the pharmaceutical industry should be considered.

Comprising approximately 120 locally and overseas owned companies, the pharmaceutical industry directly employs over 14,000 people in Australia[3] with many more jobs being created through discovery projects, collaborations and clinical trials. The industry exports $1.62 billion annually[4] and has a turnover of $6.99 billion.[5]

In terms of R&D expenditure in Australia, the industry invests over $300 million annually[6], a figure that could be substantially increased considering the quantity of investment needed to invent and develop new medications. One recent study into discovering and developing a new medicine estimated the cost per medication at US$802 million[7], and 38 new prescription medicines were approved in Australia last year.

Investment in research and development in the pharmaceutical industry is increasing, with global expenditure now in the vicinity of US$44 billion[8], a reflection of the commitment of pharmaceutical companies to continue innovation and to best utilise research discoveries from academia, collaborative projects and internal research.

There is clearly, in international terms, the capacity for Australia to make economic capital from the pharmaceutical industry. Results of this would be visible in increased employment, a greater share of GDP being generated by the pharmaceutical industry, and greater investment in R&D.

One of the most innovative environments worldwide for pharmaceuticals is the UK, employing 0.20% of total employment in the industry. By comparison, only 0.15% of total Australian jobs are in the pharmaceutical industry. By boosting the competitiveness of the industry, an increase in employment could reasonably expected; if this reached UK levels, we would see a rise of 33% in employment, or an increase of over 4,500 jobs. This would result in a pharmaceutical labour force of nearly 19,000 people as opposed to the 14,000 currently employed.

Doing similar comparisons of GDP percentages in the two countries, pharmaceuticals represents 0.1% of Australia's GDP compared to 0.54% of the UK's. Capacity therefore exists to increase both the portion and the overall total of this.[9]

[3] 1998-99 figure from Australian Bureau of Statistics (ABS) 2000, *Manufacturing Industry Australia 1998-99,* Cat. No 8221.0, ANZSIC, 2543 'Medicinal and Pharmaceutical Product Manufacturing'
[4] The data for Exports is an estimated record based on *ABS International Trade unpublished data* for commodity codes encompassing human use pharmaceuticals for the financial year ended 30 June 2002
[5] Include prescription and self-medication pharmacy sales, hospital sales and exports for the financial year ended 30 June 2000. *The value is an approximate value given the complexity of the data.*
[6] Aggregated industry data
[7] Tufts University, *Study of Drug Development,* December 2001
[8] *Drug Delivery Technology, Vol 1,* CMR International, October 2001
[9] Numbers extrapolated from various Bureau of Statistics numbers.

In terms of purely research and development investment, worldwide the percentage of pharmaceutical industry turnover reinvested in R&D is approximately 17%. In Australia, despite the high dollar figure of our investment, GSK invests only 4% of turnover in R&D.

The company believes that this number could, and should, be much higher and is committed to trying to attract more of the global R&D resources towards this market in order to align our investment more closely with global standards. If successful in this, GSK alone could see a four-fold increase in our investment in Australian R&D, a total of $100 million compared with the $25 million currently invested.

GSK's situation, considering the industry wide numbers used above, appears not to be uncommon. If these R&D investment figures could be more closely aligned in Australia with global figures, a significant increase in R&D would occur in Australia with the accrual of considerable economic benefit.

Impediments to Investment

There are significant impediments to investment by pharmaceutical companies in the Australian economy. Amongst these are these issues of access to market, and pricing and reimbursement processes that are currently causing great consternation to the industry.

These two issues are significantly undermining the competitiveness of the Australian operating environment. Earlier this year, GSK postponed the construction of a new administration building worth $25 million, and restructured its pharmaceutical commercial operation with the loss of 77 staff, due to the flow-on effect of these to our company. Research and manufacturing positions and operations were quarantined from the effect of this restructure but, if the operating environment continues to deteriorate, this isolation will cease to be sustainable.

As demonstrated above, transparency and accountability are vital to registration, pricing and reimbursement processes. The registration process in Australia is clear and transparent in respect to innovative medicines, and allows for meaningful interaction between the regulator, the Therapeutic Goods Administration and the relevant company. This clarity of process and interaction is not carried through to the listing and reimbursement processes and is of grave concern to those who wish to attract additional pharmaceutical R&D to Australia.

By comparison, as above, the regulatory system in Australia as evidenced by the Therapeutic Goods Administration performs its activities in accordance with clear transparent recognised international standards. Approval times for innovative medicines are competitive, however there is the possibility of more rapid availability with the existence of a clear and transparent priority review process. This would ensure innovative and breakthrough medicines be approved for patient use in the most timely manner.

Australia's research capacity in the areas of health and medical science is both substantial and world class. The outputs from domestic research, new technological processes, discoveries and published works, are high in per capita terms and major health and medical research clusters, such as Melbourne's Parkville Precinct, are strongly supported.

There is a high capacity to increase this, enabling Australia to move further to the forefront of health related scientific research and biotechnology. At the current time, the lack of no national coordination of science activities and attraction of R&D investment is an impediment to an "Australian R&D" investment message reaching overseas entities.

This is an unnecessary impediment – Australia has significant science abilities, good clinical research and a strong and stable economic climate that is attracting attention across the world. With many of the features needed to attract greater R&D investment in place, Australia is being constrained from achieving more significant investment in health and medical related R&D by factors entirely within our own control.

Demonstrating the Benefits of R&D to industry

Demonstrating the benefit of investment in R&D to researched based pharmaceutical industries is unnecessary – the entire existence of the industry, as suggested by our name, is dependent upon this. Investment in research and development into early discovery projects, phase I to IV clinical trials, gene technology, biotechnology and many other facets of health and medical research is the lifeblood of the industry. Without it, we would discover no innovative medicines, no breakthroughs in medical technology and save no extra lives.

The industry is therefore captive to its R&D capacity and it is unnecessary to sell to the industry the benefits that can be accrued through private sector R&D. There is a significant need however to better demonstrate the benefits of undertaking and siting industry R&D in Australia.

Australia is superbly placed to attract new R&D from the pharmaceutical and biotechnology industries. There is currently substantial work and activity being undertaken across a broad range of institutions, universities, private entities and government bodies and the level of expertise in emerging technologies is high.

Furthermore, the changing nature of the way in which many companies undertake research is changing. Many companies are now looking to collaborations to provide the expertise that they may previously have employed internally and this trend is growing. More than 50% of the products that reach the market from pharmaceutical and biotechnology originate outside the registering company – and this is growing.

This changing environment provides an opportunity to leverage Australia's research strengths in health and biotechnology and to attract a greater share of international collaborative research to Australia. To achieve this, however, a strong policy focus from government is needed.

Australia has some natural disadvantages as a location to site R&D. Principally it is, as we are all well aware, a long way from many other research centres. Although this is mitigated by the advances in communication technology, there remains the perception that distance is problematic. This perception must be overcome in order to attract additional research resources.

The majority of the steps that need to be taken to demonstrate Australia's benefits as an investment site for R&D are actually perception based and there is urgent need to change those perceptions.

Internationally, there would appear to be no clear perception of Australian R&D, partly due to lack of branding but also due to the confusion created by a lack of national coordination in this area. There are few "research brokers" to promote the benefits of doing research here and a minimal understanding about what is being done, and what we have the capacity to do in Australia.

Changing the perceptions – a vital undertaking

Australia does not present a united front to the rest of the world in relation to our research capacity and, as a result, that effort is not duly recognised. Currently various State Governments are working to attract biotechnology and other medically related research activities to their particular states, while the Federal Government has also recognised the need to encourage this research through a variety of initiatives including those progressed by Biotechnology Australia.

These initiatives are operating independently of each other and the available resources are therefore not being used to their greatest effect. For example, the competition for overseas support is often conducted by different jurisdictions attempting to attract the same, limited, overseas funding. Pooling these efforts would result in greater recognition of the value of Australian research, and facilitatea more coordinated approach to overseas projects.

Coordinating the government approach to the attraction of overseas R&D would ensure a clearer perception of Australia as a site for health and medical research investment and enhance the capacity to build an "Australian brand" in this area. GSK has recently submitted a nomination to the National Research Priorities Taskforce in the Department of Education Science and Training that a key theme for this branding be researching the National Health Priorities.

If that nomination were successful, it would draw all the strands of Australia's significant achievements in the area of health and medical research together and, in addition, clarify for overseas investors the support by the Australian Government for this area of undertaking. In this way, Australia could project itself as a key player in the research and development needed to sustain the biotechnology industries – the key industries of the 21st century.

Another initiative which would assist Australia in promoting a clear direction in its aim for higher R&D investment, is the introduction of a program designed to assist science researchers to better promote the work being undertaken here and to attract more collaborative research. In order to do this there is the need for Australia to develop a "brokerage" capacity across different research entities.

A program should be developed by which selected PhD or other researchers undertake a scheduled rotation of work with a university or other academic institution; a relevant research based private company in Australia, a similar organisation overseas and a government body. The learnings from this would result in Australia having ambassadors, or "research brokers", for local research who grasped the entire collaborative process from the academic, research, business and government perspectives.

People who participated in a rotational program like this would be invaluable to Australia. Their knowledge of decision making in relation to the location of research sites would be helpful in attracting additional research resources to Australia.

Collaborations could then be brokered both within Australia and also between domestic research and international institutions and companies.

Some research-based companies currently employ someone in this role, and having a locally based operative makes a significant difference to the capacity to attract additional research. If Australia created the capacity to train people into these roles, the ability to attract research here would be greatly enhanced.

A rotational program like this would not need to be onerous. Each research broker should rotate approximately every three to four months with the program therefore taking approximately a year. Furthermore, this could be co-funded by industry and government as it would return benefits to both groups.

The idea of rotational programs is not a foreign one, particularly in academia. The NHMRC has recommended a similar program and achieved some funding for it but this is reasonably small and would not enable the building of critical mass in this area. The involvement of private capital in this program would enable greater scope and broader training.

Conclusion

Australia's health and medical research is world standard. Our researchers possess significant understanding and expertise in many of the emerging and expanding areas of medical science - gene and protein related research being particular examples.

This area of research and development is currently experiencing a high growth period as evidenced by the significant growth in biotechnology industries, and new technologies are constantly being discovered and delivered. This environment offers Australia a unique opportunity to build its capacity in health and medical related science and to become a niche provider of the research related services required by both the pharmaceutical and biotechnology industries. This could result in quantum increases in the quantity of research undertaken in Australia and significant acquisition of emerging skills and knowledge.

The opportunity must be grasped now or it will be lost. A strong focus on these research areas, coordination of activities across many jurisdictions and levels of government and institutional bodies and promotion of Australia as a research centre all need to be introduced. If not, the current situation will pass without significant gains being made and the impact of this on research, economic and social costs will be high.