

**GlaxoSmithKline Submission  
to the  
Senate Employment, Workplace Relations  
and  
Education References Committee**

***“Inquiry into current and future skills needs”***

**Introduction**

Due to our extensive investment in Australian manufacturing and R&D and our desire and commitment to continue and increase this, GSK welcomes the opportunity to provide a submission to the Senate Employment, Workplace Relations and Education References Committee and to assist in its Inquiry into current and future skills needs. We also welcome the opportunities provided to us by the Committee to be involved in other activities of the Inquiry and to provide additional information and testimony.

GSK particularly welcomes the focus on skills that the Committee has taken as, in a global operating environment, this is a key to our Australian operations' competitiveness and capacity to continue in a time of rationalisation in manufacturing and competition for R&D locations. By addressing some of the issues involved in skills, both at the current time and looking forward into the future, this inquiry could help ensure that Australia can reap the highest possible benefit by addressing skills needs and guaranteeing that we have the skills necessary to compete successfully in the environment in which we operate.

The economic benefit that could be gleaned through enhanced pharmaceutical investment is substantial and could result in Australia becoming a niche provider of both manufacturing and research 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, R&D and chemical exports totalled \$238 million in 2002. Our manufacturing operations perform a key role as a global supplier of medicines – by the end of 2003, we will export over 75% of pharmaceutical production to 79 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 was over \$30 million in 2002 and the company is ranked in the top 20 industrial contributors to R&D.<sup>1</sup> This investment bears testimony, not only to the quality of Australian science and scientists, 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.

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<sup>1</sup> R&D and Intellectual Property Scoreboard 2001



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*<sup>™</sup>, the breakthrough treatment for influenza and *Kapanol*<sup>™</sup>, a sustained release morphine product for moderate to severe pain.

### **Drivers of Pharmaceutical Investment**

The drivers of pharmaceutical investment have been extensively researched and debated by several countries, including Australia through the Pharmaceuticals Industry Action Agenda – a copy 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.<sup>2</sup>

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

More detail on these drivers can be found at Appendix One but it should be noted that, while these provide necessary pre-conditions for investment, they are not sufficient in and of themselves to provide this.

### **Economic Benefit**

Before assessing what policy measures may be needed to ensure the necessary skills exist in Australia to attract and keep pharmaceutical investment here, the economic benefits generated 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<sup>3</sup> with many more jobs being created through discovery projects, collaborations and clinical trials. The industry exports \$1.62 billion annually<sup>4</sup> and has a turnover of \$6.99 billion.<sup>5</sup>

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<sup>2</sup> Pharmaceutical Industry Effectiveness Task Force, *Final Report – March 2001*

<sup>3</sup> 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'

<sup>4</sup> 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

<sup>5</sup> 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.*



In terms of R&D expenditure in Australia, the industry invests over \$300 million annually<sup>6</sup>, 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<sup>7</sup>, 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<sup>8</sup>, 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 be 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.<sup>9</sup>

### **Requisite skills for the pharmaceutical industry**

As indicated above, the pharmaceutical industry crosses a range of activities and, as such, seeks employees with extremely wide ranging skill sets. Outside the industry's purely commercial operations – sales, administration, finance and the like – employees and their skills can loosely be categorised into two groups: manufacturing and research and development.

Both groups of employees are highly skilled and highly qualified or trained. They require skills specific to these qualifications, but also skills specific to the pharmaceutical industry. The high levels of regulation in place across the industry mean that employees in all sectors require a high level of knowledge about these regulations and training in how to ensure compliance with these.

#### **Manufacturing**

In the manufacturing arena, there are many different areas and levels in which skills are essential. Not only are skills highly valued within specific production areas such as production engineers, but there exists a significant demand for specialists in the

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<sup>6</sup> Aggregated industry data

<sup>7</sup> Tufts University, *Study of Drug Development*, December 2001

<sup>8</sup> *Drug Delivery Technology, Vol 1*, CMR International, October 2001

<sup>9</sup> Numbers extrapolated from various Bureau of Statistics numbers.



areas of quality assurance and control, manufacturing operators on the packaging lines and staff with overlapping skill sets.

GSK also employs trades persons (fitters and electricians) responsible for the set up and on going maintenance of complex production machinery. IT trained staff are also employed with the requisite IT technical skill to ensure that manufacturing systems operate effectively.

Senior management in manufacturing are also highly skilled and require different types of skills and training from other employees. Experience of working across a large multinational company is a challenge within itself and generally ideally would require a period spent overseas to finely hone these skills and responsibilities.

### Research and Development

As outlined above, GSK undertakes a significant amount and variety of research and development in Australia. To attract this level of investment from our global company and to maintain the high quality standards required in research in our industry, the role of highly skilled, well educated and extremely motivated scientists cannot.

Principally, our scientists and those with whom we collaborate graduate with a degree in the life sciences. In addition and in line with our industry, we tend to seek employees who have worked in other areas of health science – doctors, pharmacists, nurses, academics, pure researchers – and who have a strong interest and passion for that area.

Australia is well 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.

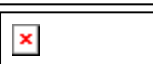
### **Concerns in relation to these skills**

GSK has some specific concerns in relation to the skills base in Australia and what this means to the company going forward. Again, these can be separated into issues relating to manufacturing and research and development, not purely because of the different skills involved, but due to the different dynamics operating in these two environments and the different directions which are being taken in addressing these issues.

#### Manufacturing

The pharmaceutical industry has been long undergoing a period of significant merger activity, reflecting the high levels of research undertaken by the industry, the risks and costs inherent in this research and the pressures resultant from this. This merger activity, coupled with international trends, has heightened the pressure on international manufacturing, leading to high levels of rationalisation in manufacturing across the globe.

Whilst GSK Australia has not been negatively impacted by this trend, the same cannot be said of other companies operating in the Australian environment in recent years. SmithKline Beecham, one of GSK's heritage companies, for example, announced the closure of their manufacturing plant in 1999, two years prior to the merger, due to a program of global rationalisation.



This has significant ramifications for manufacturing in the industry as, when the pharmaceutical manufacturing base falls, the number of people trained in skills specific to the industry decreases as does the impetus to train people in those skills. This then has the capacity to develop into a downward spiral where, as skills cease being easily available, manufacturing moves to regions and countries where these skills are more readily accessible.

The problems inherent in this situation are already becoming apparent. GSK, for example, has recently experienced challenges in recruiting an appropriately qualified quality assurance/control specialist. This is an area highly regulated by the Code of Good Manufacturing Practice and experience and understanding of this Code is critical to our ongoing business. Naturally not all qualified people have this experience and, in this particular case, identifying an appropriate candidate proved difficult.

This is not simply the case in terms of identifying someone who has knowledge of a code specific to our industry, although the above situation could arise in relation to production engineers and many other positions. Finding appropriate direct labour can also be a challenge partly as it relates to multiskilling but also when an understanding of overlapping areas or skills is required.

Multiskilling is an area which is of great concern, crossing over as it does the nexus between operational excellence and the industrial infrastructure currently in place. Ideally, a manufacturing operator on a packaging line would also possess the skills to complete basic machinery set up for the next production batch the line for the next product but in reality this job falls within the responsibilities of trades personnel.

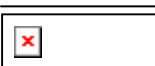
This inflexibility within the system regarding the capacity to multiskill is a limitation of our system of industrial infrastructure and, in the longer term, has the capacity to undermine the viability of pharmaceutical manufacturing. Likewise, the lack of 'knowledge overlap' is a limiting factor within the industry. There is, for example, a demand within pharmaceutical manufacturing for people who have an understanding of electrical system *and* information technology. This requirement, common across manufacturing, tends to occur particularly in areas where automation is high and a knowledge of electrical systems is insufficient without the accompanying IT skills or vice versa.

The above issues compound further in the process where the lack of flexibility and multiskilling lead to inadequate succession plans. Where people cannot gain additional skills or expand their competencies, it tends to result in those employees having insufficient skills to move to the next level of responsibility or hierarchy within an organisation. Again if appropriately skilled people are not available, this situation impedes the path to management or higher responsibilities for many staff thereby impacting the entire industry.

A final issue which is of concern is the training and experience needed within senior management. As an integral part of their work, these managers need international experience in contributing to the operations of a global company. GSK finds that it can prove difficult encouraging these staff to seek overseas experience yet it is vital to their development and to the ongoing operations of the organisation in Australia.

#### Research and development

Investment in research and development is vital for the sustainability of the research based pharmaceutical companies. From 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, there would be no innovative medicines and no breakthroughs in medical technology.

The basic science skills needed for research and development are well developed in Australia and GSK's focus in this area is very different from that in manufacturing. In R&D, Australia's main challenge is to continue to build on those basic skills to further develop people and their capacity.

#### 1. Discovery Research

Emerging and other technologies are changing the way pharmaceutical companies undertake discovery, or early phase, research. Many companies now look to collaborations to provide the expertise that may once have been 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 percentage 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 focus from both industry and government is needed.

Base level skills are not a significant barrier to Australia's viability as a location for R&D but there are some areas in which Australia is underselling itself and could do better.

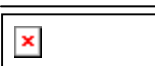
GSK, for example, employs a scientist whose sole role within the company is to 'broker' partnerships, alliances and deals with biotechnology companies, institutions, universities and other SMEs. In doing this, our Head of Discovery Research needs to understand the drivers of those small companies, the needs and expectations of government bodies and the priorities of our international counterparts who may be involved in funding the partnership.

Australia has few of these "research brokers" to promote the benefits of doing research in this country and a low level of understanding exists generally about how to progress a research collaboration, what research is being undertaken here and, at a global level, what Australian research can achieve. The skills in understanding the science involved and the drivers across a variety of stakeholders are vital in performing this role and, without these skill sets and more research brokers, Australia will fail to achieve the investment in research and development its basic science skills deserve.

#### 2. Clinical Trials

As indicated above, research and development is becoming increasingly collaborative and specific skills are needed in order to operate and compete in this area. Again, however, basic skill sets in these areas are high but other factors impact on the capacity to effectively leverage these skills to our best advantage.

Better networking opportunities, greater capacity to share best practice and more interaction between institutions, universities, hospitals and industry would assist in leveraging the skill sets already developed here. Meanwhile closer links for Australia to the international research networks would attract more early stage clinical research and enable stronger participation in the later stages of clinical development. This would strongly contribute to increasing the knowledge and skills of Australian clinicians in relation to the science they undertake but also help improve their



expertise in relation to various medicines and more effective ways of treating patients.

By building a base of stronger clinical practice, momentum would be generated for the sharing of expertise through domestic knowledge sharing networks, the training of other clinicians and ongoing collaborations. This knowledge would then be dispersed through a variety of means across a wide range of professionals in the health arena. This would not only assist in ensuring earlier access to new medicines but also help develop further Australia's strong research base.

### 3. Mentoring

The interaction between industry, institutions and other places of learning must also be promoted in relation to developing research areas. Australia does not possess a strong tradition of interaction in terms of training, learning and mentoring between these groups. Traditionally each group in the area looks internally to develop leadership skills, mentoring excellence and educational structures with the result that these skills are not consistent across the research arena and opportunities for cross-fertilisation of ideas across disciplines and research bodies often fails to occur.

## **Initiatives to Address these**

GSK is committed to working in partnership with government to devise initiatives to address the issues we experience in our operating environment. These issues are not generated solely by government and nor should industry anticipate that government has the sole role in providing solutions.

In light of this, the sections below outline some initiatives we believe could assist in the alleviation of the concerns we have and which would assist in maintaining sustainable manufacturing facilities here and building on our excellent research base.

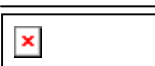
### Manufacturing

Acknowledging industry's role in the development of skills and staff necessary to its endeavours inevitably leads to the capacity and responsibility of industry to provide appropriate training for staff.

As indicated above, however, GSK is concerned that Australia's industrial infrastructure places limits on how companies can achieve this in terms of providing adequate flexibility without incurring excessive costs. GSK is more than willing to undertake this work but believes that it would be helpful for government to assist in identifying pilot programs, encouraging training capabilities and, principally, in providing the flexibility necessary for this cross-training and multiskilling to occur.

At a different level, GSK believes that graduate programs could address some of the concerns outlined above. Few graduate programs appear run in manufacturing arenas in Australia whereas in our overseas operations, they are reasonably common. Again, GSK acknowledges the company's own responsibility in establishing and running this type of course but believes that a role exists for government in encouraging introduction of these programs across industries and the training of managers of how they could, and should, operate.

Internal training is not the only solution however. Courses and qualifications across many educational bodies need to focus on the growing need for multiskilling and cross-training in the manufacturing environment. TAFE, university and





apprenticeship courses must, as an imperative, recognise the needs of industry and seek to meet these. This, coupled with increased flexibility in the workplace, would enable both the training of young people prior to their entry to the workforce and their ongoing training, and the training of their colleagues, whilst in employment. The need to achieve this multiskilling and cross-knowledge cannot be overestimated and a range of initiatives should address this gap.

In relation to currently available programs, GSK concedes a lack of adequate knowledge. This in itself is of concern to us however as, when a company of our size is inadequately informed of the programs available to us, it suggests that these are either not well communicated or well targeted to our needs, or indeed both. Furthermore, as stated above, GSK believes that there is a strong role for employment and training related programs and that these can be extremely beneficial in assisting industry reach its goals and attain greater skill levels amongst employees. This is an area where GSK would welcome the Committee's input and any information available to us.

One program GSK is confident is not being run but that we believe would be useful is one focused on an overseas program for senior management in manufacturing. We have already highlighted the need for senior management in a global company to gain experience in an overseas role but, unfortunately, this often results in their following this career path rather than bringing their learnings and additional back to Australia. Together with industry, government has a role in initiating a program to ensure that those senior management are appropriately skilled and trained but rather than those skills being lost to Australia, they return value to industrial pursuits here.

### Research and Development

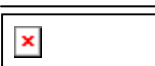
#### 1. Discovery

An initiative which would assist Australia in developing its early stage discovery research skills and capacity is the introduction of a program designed to assist science researchers to undertake the role of 'research broker'.

A program needs to 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. 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 trainee 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 recognising the fact that 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.

## 2. Clinical trials

The key drivers of clinical research are quality research, high and consistent standards and speed. Anything that improves any of these drivers assists Australia's capacity to attract additional research and will help foster networks. GSK would very much welcome the opportunity to discuss this further with the Committee but would indicate, as initial suggestions, improved processes and better understanding of pharmacogenetics on behalf of ethics committees as means as increasing Australia's international competitiveness.

There is also a strong role for industry in driving competitiveness, particularly by fostering physician-scientists and assisting in driving career pathways for people fulfilling these roles. Too often, clinician scientists enter the industry, or clinical research, by accident rather than design. Considering that these roles are vital to industry's capacity to research and develop new medicines, this role should be more strongly fostered.

Industry can assist in this by driving demand but also through more structured processes than currently exist. Replacing the ad hoc means through which clinician scientists are currently developed with a stronger identification and training program would be of assistance as would educating undergraduates and others in the role and importance of clinical research and the skills and demand for these scientists.

In addition, as mentioned above, there are gaps in the general knowledge and understanding of drug development and its place in driving biotechnology and the existence of new medicines. Industry has both the skills and capacities to assist in driving the biotechnology revolution and aiding this section's contribution to the invention and availability of new medicines. This capacity needs to be more strongly utilised and this knowledge more broadly understood.

## 3. Mentoring

Greater capacity needs to be developed for mentoring and education, not simply within one group's expertise, but utilising other groups' expertise and knowledge. Structures should therefore be made more flexible so as to enable a student within a research institute, for example, to be mentored by someone not necessarily from their own institute but from another related institute, a university or the private sector. By encouraging this, GSK is not in any way encouraging the division between research and teaching facilities but rather encouraging that greater understanding be fostered between groups in terms of each one's drivers, aims and ambitions and a greater capacity to identify and support clinical research be generated.

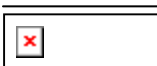
## **Conclusion**

Australia's health and medical research is world standard and our manufacturing of extremely high quality. Our researchers possess significant understanding and expertise in many of the emerging and expanding areas of medical science while our manufacturing staff have skills which have ensured the industry's viability.

Rationalisation of manufacturing and the continuing trend of large mergers in the pharmaceutical industry render this a time of high competition in relation to

manufacturing while other pressures are delivering similar challenges in the fields of research and development. The skills needed to ensure Australia is not overcome by these challenges must be recognised, fostered and built upon. The environment equally offers significant opportunities if this is achieved – the capacity to maintain and perhaps grow manufacturing coupled with the ability to significantly grow our expertise in the biotechnology industries and clinical research.

The current environment, although challenging, offers Australia a unique opportunities but these must be grasped now or they will be lost. A strong focus on our research strengths, coordination of activities across many jurisdictions and levels of government and institutional bodies and programs to address some of the limitations in our manufacturing section all need to be introduced. If not, the current opportunities will pass without significant gains being made and the impact of this on economic and social costs will be high.



## Appendix one – Drivers of pharmaceutical investment

### *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.

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.

