

SUBMISSION TO NATIONAL INQUIRY INTO INNOVATION SYSTEMS



GlaxoSmithKline

GLAXOSMITHKLINE AUSTRALIA PTY LTD

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INTRODUCTION

GlaxoSmithKline Australia Pty Ltd (GSKA) commends the Federal Government on initiating a "Review of the national Innovation System". This Review is both important and timely, in that it comes at a time when pharmaceutical innovation is continuing to move forward at a rapid pace, and is carrying with it the potential to radically change the current health system and the state of the pharmaceutical industry ('the industry') in Australia. At the same time, the process of innovation within the pharmaceutical research is subject to unprecedented challenges which has implications for Australia's ability to attract research into this industry.

GSKA is ideally placed to provide insight to the Government on issues surrounding the national innovation system from an industry perspective. GSK invests over \$35ml annually in research and development in Australia and is a participant in the P3 program. Current R&D priorities include clinical trials, support for academic research, partnerships with biotechnology companies. At any one point in time up to 70 clinical trails are being conducted in Australia and examples of research partnerships include with Australian bio-techs such as Evogenix, academic research with the University of Western Australia on genetics and our involvement as the principle industry partner with the Asthma CRC. The company has also participated actively in various government programs aimed at encouraging local investment and innovation.

The societal and economic benefits of pharmaceuticals all stem from an initial investment into health and medical research. Indeed, public support of health and medical research has been described as the best investment of public funds a government can make due to the significant returns it offers society. Research by Access Economics determined that Australian health medical research brought about a rate of return of up to five times R&D expenditure.¹

There are strong reasons for Government to adopt a stronger focus on the needs of business and industry when considering public support for science and innovation. Firstly, the competition for international R&D investment has highlighted the role Government incentives play in attracting investment from the head office of multinational companies. Secondly, public support encourages additional expenditure on R&D activity above a company's baseline level, leading to more projects which are larger in scale and which involve a greater chance of success. Thirdly, it will help Australia avoid becoming a production 'labour pool' that supplies skills and knowledge to other countries rather than accessing the potential benefits of these skills and employment opportunities through R&D involvement. Lastly, increasing the focus on the needs of industry will begin to ensure that the strong knowledge-base being developed in Australia has the capacity to both deliver ideas to Australian firms and to drive these firms into the future.

¹ Access Economics, 'Exceptional returns: The value of investing in health R&D in Australia' Canberra, September 2003.

1 Trends In Pharmaceuticals Research

Innovation and technological advances are largely responsible for the increasing cost of pharmaceuticals in the last two decades, and this is a trend that will certainly continue into the future. The pharmaceutical industry is experiencing a period of rapid change, and with this change comes the potential to transform the future role of pharmaceuticals in the delivery of healthcare.

Drug discovery and manufacture will continue to be an increasingly costly industry. Current predictions place the cost of bringing a prescription molecule to market at US\$897 million, and increasing at 2.5 times the rate of inflation.² Furthermore, only five of every five thousand pharmaceuticals developed are tested in clinical trials, and of those five only one on average is approved for patient use, meaning many compounds are the subject of substantial investments but only a small percentage of these will ultimately generate any sort of return.)

In the medium term, the application of *pharmacogenomics* is likely to create the greatest range of new possibilities for pharmaceuticals. This involves the study of how a person's genes affect the way they respond to medicines. Other research fields being explored by scientists to discover new and innovative medicines. include projects investigating bioinformatics, stem cell technology and therapeutic vaccines and are believed to carry the potential to significantly change current clinical practice and improve overall health outcomes.

Despite a significant increase in levels of expenditure on R&D within the pharmaceutical and biotechnology industries plus the advent of new technologies actual R&D productivity is declining. For example in 2007 only 22 new molecular entities were approved by the FDA compared to 53 in 1996 when R&D research was less than half the sum it is now (PWC Pharma 2020)

The declining R&D productivity is attributed to a number of factors –

- “Easy discoveries” have been made and higher level innovation carries a higher risk of failure
- Increasing regulatory scrutiny including risk adverse behaviour
- Difficulties in successfully implementing new technologies such as genomics
- Unwieldy R&D models i.e. is a large centralised R&D structure typical of the pharma industry the most appropriate structure compared to say that of small and flexible size of a biotech
- Making the transition from a bio based industry structure to the future genetics based structure

Many of the major pharmaceutical companies are under significant shareholders pressure reflecting the perceptions of “dry “ pipelines, combined with significant products coming of patent over the next few years. Many of the larger bio-techs are non-immune from these pressures. Arising from the US financial crisis there has also been a tightening up of credit facilities which is likely to impact on the creation and on-going funding of new bio-techs.

GSK's response to this issue dating back to its merger was to undertake a significant re-structure of its R&D operations. This re-structure involved a movement away from

² TUFTS Centre for the Study of Drug Discovery, May 2003. Accessed 22 April 2006.

units formed on the basis of R&D functions (eg. Molecular Biology, Organic Chemistry etc.) to the creation of a number of CEDDs dedicated to particular therapeutic areas. Each of these research units contain the scientific expertise to take a new compound and develop it into a medicine able to be tested in human populations. However, the size of these research units has deliberately been kept small in order to raise both accountability and productivity. Currently, there are eight CEDDs focussed on areas including respiratory diseases and inflammation, cardiovascular and urogenital disease, neurological and gastrointestinal research and psychiatry.

The overall industry response to the declining R&D productivity incorporate a number of approaches

- Decentralise the R&D approach away from large monolithic structures to small biotech structures. Whilst GSK and its establishment of Centres for disease research led the industry in replicating the biotech structures a number of other major pharmaceutical companies are now also following this trend
- Increased external focus on partnerships and commercial relations with academia and small start ups
- Provision of risk capital to those with “smart ideas”
- Moving R&D into those countries that have traditionally not been a source of innovation such as India, China and Eastern Europe.

For countries such as Australia this provides opportunity for the commercialisation of new discoveries as the global industry increasingly looks to external sources of new ideas outside of the US. For these opportunities to be grasped by Australian companies the infrastructure needs to be supportive in such areas as skills availability, capital availability.

2 Australia's Competitive Position

Advances in pharmaceuticals, which offer the promise of new and more effective medicines to prevent and treat disease, are dependent on continual investment in R&D. From the perspective of pharmaceutical companies, this R&D is complex, carries high risk and comes at a high cost to developers. Given the risks involved with these kinds of outlays, it is important that government continues to invest in medical R&D to ensure sufficient incentives exist to encourage industry to continue to undertake innovative health and medical research.

Globally, health and medical research is a growth industry. Many countries are now acting on the realisation that investment in R&D is a critical component of the economic prosperity of any nation. India and China have recently made significant investments into the R&D sectors of their countries, the European Commission is aiming to increase investment in European R&D to 3% of GDP by 2010 and the United States have declared an intention to double their federal commitment to research programmes over the next ten years and make permanent their tax credit research expenditures. In this context, it is important that Australia's investment in science and innovation keeps pace with international trends.

In light of the need to keep pace with the level of support internationally for science and innovation, GSKA welcomes past initiatives to increase funding for health and medical research. The investment of \$500 million over four years for the provision of

additional grants through the National Health and Medical Research Council (NHMRC), and the \$170 million over nine years to establish a research fellowship scheme through the NHMRC, are positive initiatives that will help to boost the level of medical research undertaken in Australia. Similarly, the funds provided for the development of Australia's physical R&D infrastructure will act as a further incentive for more researchers to become involved in R&D within Australia and will provide them with the facilities and equipment necessary to develop the medical breakthroughs of tomorrow. GSK also supports the Higher Education Endowment Fund as a concept, recognising the need to be clear around its intent.

In particular GSK welcomes the change of the beneficial ownership test to allow the company to claim for R&D conducted in Australia where the IP is held overseas, plus the increase in tax concessions.

Such increases in public support act as an indirect stimulus for business investment in this area, as more significant and large scale projects encourage collaboration with industry and innovative companies seek to invest in emerging research in order to ensure the full economic potential of any discoveries are captured.

Whilst these announcements were a positive step forward, more clearly needs to be done in order to lift the level of support in Australia for science and innovation back up to international standards.

3 Areas Requiring Attention in the Innovation System

From GSK's experience, Australia has a number of significant advantages as a source of investment including general skills levels, a growing entrepreneurial culture, a strong medical/science history, supportive Governments, stable political environment. However there are areas within the Innovation system that need attention

- The need for a regulatory system that minimises delays in enabling new products to come to market and in conducting clinical trials in Australia
- Removal impediments to R&D commercialisation by SMEs such as tax implications of selling business
- Maintaining levels of appropriately skilled personnel
- Improved linkages between industry and academia based on a commercial footing
- Non risk adverse capital availability including the provision of incentives that minimise risk in the initial commercialisation process
- Awareness of Australia as a source of innovation
- Disparity of support programs of which no-one program is "large" enough to gain head office attention

3.1 The Need for Initiatives Driving Innovation in the Pharmaceutical Sector

Government programs designed to stimulate business investment in science and innovation are an important means of ensuring Australia remains competitive in terms of its R&D intensity and realises the substantial economic benefits that stem from an active research sector

A number of programs have been put in place to encourage investment in R&D activity in Australia. However, these programs generally exclude larger

companies from accessing the funds or have other requirements that can reduce their value to industry. Indeed, the Innovation and Incentives Working group established in 1999 stated:

There has been a significant change in the focus of government incentives to encourage industrial R&D, with much greater emphasis being placed on R&D start grants...the effect of this shift has been to focus greater attention on the R&D efforts of small firms...whilst the Working Group commends this increased focus on smaller firms, we believe the policy pendulum has moved too far towards the granting side.

Various initiatives have been put in place by the Federal Government in order to encourage BERD. The programs that have had the most significant impact on the pharmaceutical industry in this regard have clearly been the R&D tax concession, co-operative research centres and the Pharmaceutical Industry Investment Program (PIIP), later replaced with the Pharmaceuticals Partnerships Program (P3). However, these initiatives have enjoyed varying degrees of success.

Therefore, the following section will contain a focussed discussion on the effectiveness of the above initiatives as mechanisms of public support more directly targeted at larger firms involved in innovative research and in encouraging additional research (additionally).

3.2 Improving the Value of Current Public Support for Pharmaceutical Innovation

Research and Development Tax Concession

The R&D tax concession is currently the principal initiative to increase the amount of R&D undertaken in Australia. In the 2006-07 Budget, the programme was estimated to provide \$414 million in tax concessions to Australian businesses for their R&D activities each year.³ It is a well-accepted incentive with low compliance costs. The recent changes to the beneficial ownership provision has increased the attractiveness of the concession.

Given that the tax concession is designed to promote increased R&D in Australia the issue is whether it encourages new activity versus rewards activity that would have occurred anyway. From GSK's perspective investing in R&D is dependent on a number of factors of which skills availability is crucial as is Gov support. As a company we believe that a grant scheme is preferable to a tax concession at the current rate as it provides more of an opportunity to attract strategic R&D by bidding internally for projects – if the current tax concession was of a magnitude greater it would provide more a strategic lever. However GSK appreciates that there are many competing areas of demand for gov funding .

However, it should be noted that such tax incentives are not unique to Australia but rather could be considered a minimum standard for an active R&D sector when compared to other international benchmarks. Many competitor nations now offer their own types of tax incentives to stimulate both local and international investment in science and innovation.

³ The Hon Ian MacFarlane MP, Media Release, 'R&D Tax Concession – A Winner for Business' 9 May 2006.

Factor (f), PIIP and P3

Government initiatives directed at industry such as Factor (f), PIIP and P3 offer significant potential to enhance innovative R&D within the Australian pharmaceutical sector. They offer a practical incentive for firms to make substantial R&D investments that will ultimately bring about economic gains for Australia. However, the design of these programs is clearly critical to them having this desired effect.

From an industry perspective, the design elements present in Factor (f) and PIIP offered a far greater incentive to increase current levels of R&D investment than that offered by its successor, P3. Overall P3 offers smaller financial incentives which are open to a far greater number of participants. Programmes of this nature are of more benefit to the smaller biotechnology firms due to their greater ability to significantly increase their R&D expenditure from a smaller base, the lower compliance costs experienced by smaller firms and the greater attractiveness of smaller grants for their early-stage research.

There are a range of other funding options open to smaller companies involved in pharmaceutical research such as Commercial Ready and COMET. Therefore, GSK submits that allowing smaller companies to access funding under P3 has only diluted the effectiveness of this mechanism of public support for innovative research by those members of the pharmaceutical industry which are precluded from accessing other forms of financial assistance. This opinion accords with previous statements made by the Productivity Commission in their review of PIIP, including the recommendation that "participation in any modified PIIP should, therefore, be restricted to firms supplying the PBS".

A government initiative that offered more substantial incentives, targeted towards the larger firms in the pharmaceutical sector, would be a more effective addition to current public support initiatives for science and innovation. It would compensate those currently unable to access the R&D tax concession and various other programs available to smaller firms; it would combat the perception of price suppression flowing from the operation of the PBS; it would stimulate larger scale investments in R&D offering real economic benefits through increased employment and commercialisation opportunities; and it would indirectly assist smaller firms through increasing collaborative projects.

Cooperative Research Centres

Cooperative Research Centres (CRCs) are another important means by which Government supports science and innovation within Australia. GSK is currently involved in the Cooperative Research Centre (CRC) for Asthma and Airways. In its current form this CRC consists of a joint venture between GSK, Pharmaxis, the Garvan Institute, Woolcock Institute of Medical Research and four partnering universities. Our participation in the asthma CRC has provided access to top researchers and new research, and of course to government funding in an area of research that is in the public interest.

The role of CRCs in encouraging collaboration and partnership is increasingly important in the pharmaceutical sector due to the rising investment in extra-mural research by pharmaceutical companies. Increasing the utilisation of external expertise and resources, particularly for discovery research, is a global trend in industry, as companies turn more of their focus towards the clinical testing of compounds.

However, whilst CRCs are an effective use of public funds for ensuring collaboration in research, it should be understood that the challenge of commercialising research is often more effectively done through other means. For example, the commercialisation of a particular innovation from a CRC can often be undermined by the role of industry partners being limited to the provision of funds. In addition, when many industry partners are present in a CRC, competitive and confidentiality concerns may compromise their ability to assist significantly in the research program. The need for exclusive rights to intellectual property (IP) also hinders the value to individual companies of large CRCs with many industry partners from the pharmaceutical sector. This sets the pharmaceutical industry apart from other sectors (such as the wine industry) in which mere production of technology for use by all parties is of value. However, for the development of medicines exclusivity of rights over a new innovation is critical to its commercialisation, and this hinders the ultimate value of many CRCs in this area. Indeed, this was the experience of GSKA during the first incarnation of the Asthma CRC (see Box 5.3).

GSK submits that whilst CRCs are a positive initiative, they represent just one link in a longer 'supply chain' of R&D. As such, CRCs should not detract from the need for further industry specific programs – such as PIIP/P3 – that can offer further public support for the commercialisation of innovative products. Indeed, better coordination between these types of programs could enable the objectives of increased collaboration and more effective commercialisation to come together.

GSK believes that there is scope to modify the operations of the CRC which is based on the one model of partnership to create three classes of CRCs which would align incentives and structures with the objectives of the program. We would suggest the creation three kinds of CRC grant, public good, commercial and research infrastructure. Each CRC type would have its own separate review panel and budget appropriation set by Gov.

Public good – Whilst the objectives of such a CRC might include IP the overall intent is to focus effort on benefits to Australians as a whole eg research into climate change impacts. In such a scenario the incentive for industry involvement which would essentially be of an altruistic nature is limited. GSK would propose that industry contributions to such a CRC obtain a 200% tax write-off as an incentive subject to the establishment of appropriate parameters. Should a commercial participant licence the IP they would be required to repay the tax write-off.

Commercial CRC. – Consortium formed to progress development of commercial assets. Outcome would be new IP or adding value to IP (such as progressing a biomedical compound or program towards or into the clinic). It is important that Industry leads these bids rather than being secondary behind academia. The selection Interview must be lead by the industry partner and total cash + in kind from industry must exceed a fixed percentage (say 25%) of the total party's contribution. To encourage optimal exploitation of new IP, industry should own new IP (offshore or onshore). However, each bid should be explicit in describing the mechanisms for returning the value to Australia through milestones, royalties, success fees .

Innovation Engines: This is not a grant to establish new capital investment per se but would be intended to develop equipment, expertise networks or other resources which might lead to a competitive position in a particular area or science. It should focus on technologies that have broad application and for which the technology is

developing rapidly. The quality of bid for this kind of CRC should not be on the basis of IP or compensable assets but in supporting consortia that might develop platforms or innovation engines which is likely to give the nation a competitive position in new or evolving technologies.

4 Rationalisation Of Support Mechanisms

Currently, there are a large number of collaborative research programs in existence. These include programs administered by the Australian Council (linkage grants, centres of excellence and special centres of excellence), the NHMRC (Centres of Clinical Research Excellence and program grants for broadly based collaborative research), DEST (CRC Program), AFFA (the Rural Research and Development Corporations), and CSIRO (the flagship program). The Australian Stem Cell Centre and the National Information and Communication Technology Centres of Excellence are also examples. There are also some individual offerings which are too small to achieve meaningful outcomes and are unlikely to generate interest.

Collaborative research programs should return value to the Australian tax payer and all collaborating partners. For research intensive firms such as GSKA, that are highly research-intensive, fully global and operate with very long cycle times from discovery to commercialisation, collaborative programs must:

- be of a size and scale to attract critical mass of researchers and industry funding;
- be of a size and scale to attract international attention - this will serve to generate additional investment and attraction of skills;
- encourage the creation of research centres with capabilities that are truly globally competitive;
- conduct quality research that is world class and novel;
- have funding that is long term i.e. ten years;
- be commercially focussed and industry driven;
- have few industry partners to ensure exclusive access to research results;
- be sensitive to commercial partner needs regarding rights and ownership to the outcomes from the research (mainly IP); and
- have application and reporting requirements which are not overly complex or disproportionate to the value of the program.

Most of the collaborative programs listed above do not meet such criteria. The Australian Stem Cell Centre is a good example which is creating some critical mass in a defined area of medical research. It is recommended that the Government undertake work to review the suite of collaborative research programs to ensure they are meeting both the needs of the research base and industry.

5 Funding Reviews Of Research Grants

Funding reviews of research grants by the national bodies utilise a scoring systems in which each grant application earns points against a number of predetermined criteria. One simple idea that would encourage greater commercial focus would be to make a predetermined but balanced number of bonus review points available for grant application that have, say, greater than 10% funding from an industrial sponsor. Not only would this be expected to increase the attractiveness of commercially relevant projects, but the availability of the points would be expected would encourage researchers to seek input from industry to the relevance of project before submission of research grants. GSK would propose that a pilot of this concept be attempted in a selected therapeutic or technical area of biomedical research in order to determine its merits and practicality.

6 Taxation Of Losses For Bio-Tech Companies

There is uncertainty how several ATO tests for the recognition of tax losses may be applied to Biotechnology companies. The nature of the biomedical R&D is such that biotechnology companies would be expected to incur significant tax losses over sustained periods before reaching profitability. While the interpretation of these tests to more conventional business models is straightforward, the nature of the Biotechnology business model, where a company in its loss making phase might undergo multiple funding rounds or changes in the R&D portfolio, can lead to uncertainty as to the ability of a such a company to claim tax losses. These uncertainties can impact on the valuation the companies which can have repercussions such as the ability of the biotechnology companies to raise capital. Clarification of the tests are needed to ensure the viability of the biotechnology company business model.

7 Risk Sharing Grants

A long standing complaint for many small start up operations is the lack of capital at the start up stage – it is acknowledge that much has been done in this area to improve capital availability, dating in fact to the previous Labor Government. GSK believes the Government could assist in promoting early stage deals by sharing up front risk. The deal can be a licence to IP or a collaborative project providing the deal contains upfront payment and milestones.

When a biotech or uni (licensor) signs a deal with a biotech/pharma (licensee)

- the deal has an up-front payment and at least two milestones
- 75% of up-front fee provided by gov as an interest free loan
- 50% of loan returned to Gov in each of the first two milestones
- Gov establishes a fixed fund for support of such funding - milestone re-payments would come back into the fund. Amount available under fund fixed and set by annual allocation to the fund plus money payed back into the fund through milestones,
- focus on larger deals - up front + 1st 2 milestones must exceed a threshold value (say \$2M but be below \$10M), excluding royalties.
- Deal must be embodied in a legally binding agreement - supplied in strict confidence to Gov.

Example - Deal structure - biotech/pharma

	Without program	With program
up front	Pharma pays biotech \$1.2M	Pharma pays \$1.2M to biotech - Gov pays \$0.9M to Pharma
1st milestone	Pharma pays biotech \$1.2M	pharma pays \$1.2M to biotech and 0.45M to gov
2nd milestone	Pharma pays biotech \$2.4M	pharma pays \$2.4M to biotech and \$0.45M to gov
Total	Pharma pays \$4.8M	pharma pays \$4.8M

Back loading of the financial risk to the licensee makes early stage investment more attractive. GSK believes the program would result in more funding of riskier (earlier) projects by industry.

8 Addressing Skills Availability

Industry Rotation Funding

GSK suggests a new program designed to encourage academia exchange/rotation which should target early-mid career academics spending time in industry (either in Aus or overseas) and mid career industry scientists (in Aus or overseas) to spend time in academic institutions in Aus

GSK also proposes a fund to support such exchanges internationally. The fund would pay costs incurred by the host entity in supporting the exchange and provide backfill for the donor entity and cost of living differences to the person undertaking the exchange.

Advantages of such an approach would encompass:

- Improves academic training for commercial research (fit for purpose)
- Provides leads on industry problems (seeds new projects in academia that meet industries needs)
- Create networks between industry and academia.

Addressing Awareness

GSK along with a number of companies in Australia employs a R & D Alliances officer whose role is to interface with the Australian research community in regard to possible areas of interest with GSK. This has lead to a number of commercial partnerships being initiated between Australian bio-techs and GSK as well as investments in academic research. Employing such a specialist resources helps combat the “tyranny of distance” Australia still faces in raising awareness of our capabilities. GSK’s experience is that once people physically visit Australia they are more than not “blown away” by the capabilities available.

GSK suggests that the employment of such discovery officers should be a 100% tax write off so as to encourage other companies to invest in such positions. It is appreciated that there would need to be tight guidelines around the tasks performed for such a funding concession.

Clinical Trials

The need to enhance the globally competitive position of Australia for attracting R&D based Pharma-sponsored Clinical Research to Australia.

Australia has a proud history of conducting innovative and high quality clinical research which has informed public health decision-making. The last 20 years has also seen a significant growth in pharmaceutical industry supported clinical trials across all phases of clinical development. In a global context, Australia has been seen as a relatively attractive place to undertake high quality clinical trials, at a reasonable speed and cost.

Undertaking clinical trials in Australia benefits Australia through skills development, access to latest technology and research trends, academic support, international linkages.

However, the exponential increase in cost of drug development, the increased Regulatory requirements, and the pressure to shorten development times has driven the global pharmaceutical industry to look beyond the traditional countries in which to conduct clinical trials viz. Western Europe and the USA. Indeed there has been significant increase in the placement multinational multicentre clinical trials in emerging markets such as the Asia Pacific, Latina and Central & Eastern Europe (CEE) – where costs are lower and access to patient populations is far greater.

GSK (*as with other multinational pharmaceutical companies*) has invested significantly in developing clinical trial capabilities in many countries, and each subsidiary Operating Company Medical Department, competes for participation in trials – against pre-specified criteria of speed of conduct of trials, the cost and quality.

In recent times GSK globally has undertaken an extensive review of its Clinical development operational model and has determined to rationalise the countries in which it will undertake Clinical trials, to reduce complexity, improve productivity and reduce costs. Whereas previously an average of 10 countries may have been involved in a typical Phase 2 or Phase 3 clinical trial, this will now be reduced to approximately 7 countries, making the internal competitive landscape for participation of countries much more fierce – hence increasing the risk to Australia of not being selected for participation.

GSK is also seeking to improve operational efficiencies by including less clinical research centres globally in each trial – the selection of these sites will be based on the research infrastructure, excellence in track record and potential for patient delivery, willingness to partner with Industry, and the critical mass (number) of patients that can be enrolled in clinical studies. Australia's current track record of volume of patients participating in Phase 2 & 3 trials per centre is far less than that what is being achieved by emerging markets (This in turn makes Australia relatively more expensive (and less productive) based on a number of internal metrics.

These challenges that threaten Australia's position as a leading country to undertake clinical trials are not unique to GSK, but rather common to all major International R&D based pharmaceutical companies. Over the last 3-5 years we have seen a significant shift of new trials placed in emerging markets (CEE, Asia Pacific, Latin America). At GSK, this has increased from approx. 10-15% in the early 2000's to almost 50% of new patients being randomised in trials from emerging markets in 2007.

The challenges and threats to Australian clinical trials have been recognised by the Pharmaceutical Industry Council (PIC) R&D Task Force (supported by the Australian Government, Dept of Innovation, Industry, Science and Research). This Taskforce has highlighted four underlying “pillars” which are critical to attract Clinical Trials to Australia and to ensure Australia remains internationally competitive.

These “pillars” are:

- Quality
- Timeliness
- Cost
- Capacity

What’s needed to Sustain and Grow Multinational Pharmaceutical Industry Investment in Clinical Research?

If Australia is to sustain and grow its Multinational Pharmaceutical Industry investment in clinical trials, a National and State Strategic and action plan needs to be developed urgently and implemented, which will involve the very many stakeholders. This will need to be supported by Government at both Federal and State level, and the various departments, including Depts of Industry and Innovation, Health, the NHMRC, TGA and Industry partners, researchers, their staff, Hospital General Managers and administrative arms such as Research office staff, Ethics committees etc.

It is only through a commitment at all levels and a coordinated approach can Australia best harness its capabilities and opportunities to make a significant difference to our global competitiveness in clinical trials. Resources must be available to undertake a full assessment of the current investment in Industry funded clinical trials, and assess the current strengths, weaknesses, opportunities and threats of our Clinical Research environment. Some of this has already been obtained by the Pharmaceutical Action Agenda, however, this proposal is for the focus to be on Pharma -Industry sponsored trials.

There are many identified areas which Australia must focus to improve its clinical trial performance and some examples are listed below:

Timeliness for Initiation of Clinical trials:

- Streamline and speed up the Ethics approval process for multi-centre clinical trials Nationally.
 - Some State’s have been trying to effect positive change, with varying degree of success To make significant advances Australia needs a National solution. Although the NHMRC have it on their agenda, progress is slow. At a State level, the NSW has managed to streamline the Ethics approval process, but the ability to start trials quickly has been hampered significantly within public Hospitals by the inadequate and inefficient Research Governance review. There is an urgent need for the Hospital/Institution Research Office’s to have appropriately trained administrative resources to expedite research within the public system.

- General Managers / CEOs in Public Hospitals be given incentives to attract pharma-sponsored clinical research into their institutions as part of their performance assessment.
- A National Ethics application submission process for clinical trials which is adopted and accepted universally.

Capacity for the Conduct Clinical Trials:

- Enhance community awareness (and education) of the importance of clinical trials.
 - Collaboration with Consumer groups
 - Understand motivators to enhance patient participation in trials
- Encourage (through incentives) the development of multinational clinical research centres “Hub sites” that can focus on rapid recruitment of patients and their clinical management in Pharma-sponsored trials
- Development of clinical research centres in “Regional” areas of high patient catchment areas
- Encourage the increase of referral networks for patients to participate in trials
- Enhance coordination / collaboration between Hospitals for the same clinical trials to increase throughput per research unit – which will increase efficiency and decrease costs.
- Encourage GP networks to participate in trials (e.g. Divisions of General Practice)
 - Incentives, CME points, infrastructure support
- Education of medical schools
- Develop a programme to increase a qualified and competent Clinical Research workforce to undertake clinical trials.

Conclusions

Medicines have clearly had an increasingly important role in society. Past advances have made significant contributions to the overall health, well-being and longevity of society, and future innovations have the potential to take these health and economic benefits to a new level.

Significant public funds are currently committed to a number of programs directed at assisting the biotechnology sector, yet larger scale investment into health and medical remains to an extent neglected. Each of the major sources of public support for larger scale investment in science and innovation (the tax concession, PIIP/P3 and the CRC program) could be better designed to target the activities of members of the pharmaceutical industry. Indeed, there is a pressing need for industry-specific programs that can stimulate investment in science and innovation in a real way within Australia.

Health and medical research is a growth industry, and one with an outstanding record of achievement in both monetary terms and through returns to our society. New discoveries are now our best defence against the future challenges facing society such as the ageing population and the increasing burden of chronic disease. Therefore, it is critical to ensure that adequate public support is in place to enable Australia to bring these discoveries to the world.

GSK's submission addresses a number of key areas where new programs would strengthen the nation's ability to attract research and development. The proposals within this submission focus on ensuring support for new research and development is of a magnitude to induce additionally, rather than rewarding activities that would have occurred, encourage greater industry academia linkages based on commercial terms, encourage bio-tech start ups, strengthen Australia's position to undertake clinical trials.

Taken together the package of recommendations by GSK are targeted at ensuring Australia is in the position to benefit from the greater focus by the pharma industry on external sources of new ideas.

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GlaxoSmithKline – Background

GSK is a world leading, research-based pharmaceutical company with a powerful combination of skills and resources able to meet the healthcare needs of people around the world in order to help them to do more, feel better and live longer. The company is a global leader in the research, development, manufacture and supply of prescription medicines, vaccines, over the counter medicines, oral care products and nutritional healthcare drinks. GSKA employs approximately 1500 staff and its contribution to Australia's export revenue through pharmaceutical and consumer healthcare exports totalled \$A330million in 2004. Its manufacturing operations perform a key role as a global supplier of medicines, exporting 65% of pharmaceutical production to more than 80 countries throughout Europe, America, Africa, Asia, the Middle East and the Pacific Region.

As a predominately research based company, GSK is committed to sustaining its current R&D intensity and investment, with a global R&D budget of £2.8billion (A\$6.8billion) annually. UPDATE In recent years, GSK has re-designed its R&D operations through the creation of Centres of Excellence for Drug Discovery (CEDDs). See Table 1 This innovative approach has helped GSK develop a significant product pipeline, with many new chemical entities (NCEs) and vaccines in clinical development.

At any one time, GSKA is conducting approximately 80 clinical trials in Australia involving approximately 250 investigating clinicians and 10,000 patients. In addition, our discovery research collaborations with respected Australian scientific institutions are targeting the increasingly important area of genetic research and investigating key health challenges including Alzheimer's, cardiovascular disease, diabetes, hepatitis B, immunology, migraine, metabolic pharmacology, respiratory medicine, oncology and rheumatology. As examples, two of the collaborative projects in which GSKA is involved are included in Table 2.

Table 1 : GSK's Centres of Excellence for Drug Discovery (CEDDs)

The Creation of GSK's CEDDs

When GlaxoWellcome merged with SmithKline Beecham in 2001, the newly formed GlaxoSmithKline undertook a significant re-structure of its R&D operations. This re-structure involved a movement away from units formed on the basis of R&D functions (eg. Molecular Biology, Organic Chemistry etc.) to the creation of a number of CEDDs dedicated to particular therapeutic areas. Each of these research units contain the scientific expertise to take a new compound and develop it into a medicine able to be tested in human populations. However, the size of these research units has deliberately been kept small in order to raise both accountability and productivity.

Currently, there are eight CEDDs focussed on areas including respiratory diseases and inflammation, cardiovascular and urogenital disease, neurological and gastrointestinal research and psychiatry. The task of each of the eight CEDDs is to identify lead compounds with therapeutic potential and take them through proof-of-concept studies in order to produce a clinical candidate with strong evidence of efficacy. A significant part of the pre-clinical R&D GSKA conducts in Australia inputs into one or more of these CEDDs.

The importance of the GSKA's strong research base in Australia, and the company's ability to respond to the needs of Government, is demonstrated by GSKA's steps to scale-up its manufacturing capacity for the supply of the antiviral Relenza in response to a potential pandemic flu outbreak. This initiative is part of a broader strategy to expand and enhance the company's manufacturing capacity and research capabilities in both vaccines and in antivirals, and demonstrates the ability of GSKA to work with Government so as to bring about solutions.

Table 2 : Examples of the GSK Early Stage R&D Collaborative Activities

Genetics screening laboratory – Perth

Supported by recurrent funding and capital support, the Perth laboratory of the Australian Neuromuscular Research Institute at the QE2 Hospital in Perth is one of a small number of sites around the world supported by GSK to undertake genetic screening work.

The Perth laboratory compares genetic samples of healthy and disease-state individuals in an attempt to find genes that are associated with the cause or susceptibility of major diseases. This effort includes the search for and use of single nucleotide polymorphisms (SNPs), a small number of which are already known to be markers for disease inheritance for conditions such as sickle cell anaemia and Alzheimer's. This information is then used to identify potential new targets that may be used to identify new medicines.

GSK supports the laboratory through the provision of financial support for expenses and staff, as well as funding the purchase of expensive, cutting-edge equipment to facilitate the laboratory's work.