21 September 2012

Chris Jordan
Chair, Business Tax Working Group
The Treasury
Langton Crescent
PARKES ACT 2600

Dear Mr Jordan

Thank you for the opportunity to contribute to the Business Tax Working Group's review of Australia's business tax system and particularly the Working Group's consideration of possible mechanisms to offset the cost of introducing a cut to the company tax rate.

Medicines Australia represents the research-based medicines industry in Australia, which brings new medicines, vaccines and health services to the Australian market. In 2011-12, our industry generated over $4 billion in exports and for the third consecutive year, invested over $1 billion in research and development.

Medicines Australia strongly supports a cut in Australia's corporate income tax rate because it will boost this country's global competitiveness and make it more attractive to global investors. However, we have serious concerns about some of the options being considered by the Business Tax Working Group to help "pay" for such a cut.

In particular, we are concerned about proposals to change the newly implemented R&D Tax Incentive in ways that would seriously undermine the ability of Australian companies to attract foreign investment in R&D.

Specifically, Medicines Australia would strongly oppose:

- the abolition of the non-refundable component of the R&D Tax Incentive (Option C.1), which is the **only** program available in Australia to encourage companies with an annual turnover of more than $20 million to invest in R&D and which was explicitly used by Government as justification in 2009 for discontinuing support for the pharmaceuticals industry in Australia for the first time in 20 years; and

- the reduction of the rate of the non-refundable tax benefit from the existing 40% to 37.5% (Option C.4).

  At the current level (40%), the R&D Tax Incentive provides a globally competitive tax incentive for conducting R&D in Australia.[1] Cutting the rate would mean that

[1] A recent report by KPMG Global placed Australia at the **top** of its ranking of the most competitive locations for R&D investment, ahead of Canada, the United Kingdom, the Netherlands, Mexico, the United States, France, Japan, Germany and Italy. According to KPMG, the improvement in Australia's ranking is the "result of its adoption of the new R&D Tax Credit system". Moreover, a recent report by a Canadian accounting firm, Scitax Advisory Partners, also showed that the new Australian system delivers a far simpler (and more competitive) tax incentive to companies conducting R&D in Australia, compared to Austria, Canada, China, France, Germany, India, Ireland, Mexico, the Netherlands, New Zealand, South Africa, Spain, the United Kingdom and the United States.

other countries, which offer more generous tax incentives, would attract an even greater share of global R&D investment than they do now, obviously at Australia's expense.

- Medicines Australia would also oppose excluding companies with a group aggregated annual turnover of greater than $10 or $20 billion from being eligible to claim tax benefits under the existing scheme (Option C.2)

  Multinational bio-pharmaceutical corporations operating in Australia account for the vast majority of private investment in medical research in this country. Most of these companies have global annual turnover well in excess of the proposed $10 or $20 billion limit. If the turnover limit were applied to a company's global turnover and not just to an Australian subsidiary's turnover, many multinational corporations operating in Australia would be ineligible for the R&D tax credit incentive. We note that companies would be able to deduct their R&D expenditure under normal deduction provisions, but this would be an insufficient incentive for global companies to increase or even maintain their R&D investment in Australia.

  If the turnover threshold was applied only to the local Australian company group turnover, including affiliates and associated entities, Medicines Australia would not oppose a modified option C.2. None of our member companies' Australian operations would exceed a turnover threshold of $10 billion.

Medicines Australia could potentially support the imposition of a cap on the amount of eligible R&D that can be claimed annually under the non-refundable component of the R&D Tax Incentive (Option C.3). There are no medical biotechnology or pharmaceutical companies operating in Australia, including members of Medicines Australia, that currently surpass the proposed $100 million (annual) cap. However, we would strongly caution against this option on the grounds that the R&D Tax Incentive was implemented to help **increase** the level of R&D investment in Australia; capping the level of eligible expenditure could, inadvertently, stop or at least slow the rate of growth in annual R&D expenditure in not just our sector but across all industry sectors.

Medicines Australia believes that it is essential for Australia to remain a competitive location for foreign and domestic R&D investment. Among its other benefits,[2] this investment:

- supports high-skilled jobs across Australia, including around 13,000 in R&D alone;
- underpins the long-term commercial viability of a growing and increasingly export-oriented Australian medicines industry;
- plays a vital role in improving Australia's healthcare system; and, above all,
- allows Australians to live longer, healthier and more productive lives.

Given that the stated purpose of reducing the corporate income tax rate would be to "increase Australia's ability to attract foreign investment", it would seem

[2] Medicines Australia strongly urges the Business Tax Working Group to refer to our recent submission in response to the Government's Strategic Review of Health and Medical Research in Australia (Attachment 1) Our submission explains in considerable detail why it is important for Australia to remain a competitive location for R&D investment and provides a full description of the considerable spillover benefits for the Australian economy from private investment in medical research. A copy of our submission is attached to this letter.

counterproductive to implement other policies which would seriously undermine the ability of Australian companies to attract foreign investment in a high-value area like medical research.

Medicines Australia was one of the earliest and strongest supporters of the implementation of the R&D Tax Incentive. The new system replaced a system which had failed to help the Australian medicines industry attract a larger share of the global medicines industry's R&D investment budget, which is worth more than $70 billion annually. The old system – the R&D Tax Concession system – was unpredictable, overly complicated and required local companies to demonstrate year-on-year growth in their R&D expenditure in order to secure a (relatively insignificant) tax benefit.

The new R&D Tax Incentive, which was implemented after nearly three years of extensive community consultations, was specifically designed to make access to tax benefits more predictable. In addition, under the new system, there is no requirement for companies to demonstrate year-on-year growth in their R&D expenditure in order to claim a tax benefit, nor is there any requirement for intellectual property from an eligible R&D project to be held in Australia. Above all, the new system provides a globally competitive tax incentive for conducting R&D activities in Australia. Together, these attributes of the new R&D Tax Incentive are already helping companies in our sector to better demonstrate to global headquarters the advantages of sending R&D investment to Australia.

Abolishing or changing the R&D Tax Incentive barely eighteen months after it was implemented would send the worst possible signal to global investors and harm Australia's reputation as a stable and predictable business environment. Medicines Australia would strongly urge both the Business Tax Working Group and the Australian Government to let the program operate in its current form for the foreseeable future, not least because if the operation of the Tax Incentive does have unexpected (and undesirable) consequences in the longer-term, these can be remedied when the entire system is reviewed in 2014 (as per a legislative requirement for the Commonwealth to initiate a comprehensive review of the program three years after its implementation).

If you have any questions about statements in this submission, please do not hesitate to contact me on 02 6122 8500.

Yours sincerely

Dr Brendan Shaw
Chief Executive

Attachment

1. Medicines Australia's submission in response to the Government's Strategic Review of Health and Medical Research in Australia

Attachment 1

30 March 2012

Mr Simon McKeon
Chairman
Strategic Review of Health & Medical Research
PO Box 4226
MANUKA ACT 2603

Dear Mr McKeon

Thank you for the opportunity to contribute to the Strategic Review of Health and Medical Research in Australia.

Medicines Australia represents the research-based medicines industry in Australia, which brings new medicines, vaccines and health services to the Australian market. In 2010-11, the medicines industry generated nearly $4 billion in exports and for the second consecutive year, invested over $1 billion in research and development (including more than $630 million on clinical research).

For decades, the medicines industry has been a crucial component of Australia's health and medical research system. By investing heavily in research and research partnerships, the industry has both facilitated and enabled the commercialisation of important Australian discoveries such as the HPV vaccine for cervical cancer and an antiviral drug used to prevent or shorten the duration of a flu infection. Furthermore, with access to a global network of companies, researchers, payers and patients, the medicines industry in Australia has been and will remain an efficient and cost-effective conduit for Australian scientists and Australian start-up companies to bring their research and innovative products to the world. For these and other reasons discussed in this submission, it is essential for Australia to maintain its reputation as a high quality producer of research, and continue to be able to attract foreign and domestic investment in medical research.

Unfortunately, the task of being globally competitive is becoming increasingly difficult for Australia.

As a result of years of significant public and private investment in higher education and medical research, Australia is home to some of the world's best scientists and health professionals and boasts a world-class research infrastructure, a stable socio-economic environment, a relatively strong intellectual property system and an efficient regulatory regime. These are all factors that have contributed to the strong growth of overall investment by (among others) the medicines industry in Australia over the past several decades. But these factors alone are no longer proving sufficient to attract investment to Australia.

Several reasons can be given for this. The most important among them is the emergence of developing countries – especially in Asia and South America – as viable alternative destinations for large and long term research investments.

Until recently, many of these countries were ignored as potential competitors for research activities due to the lack of local expertise, their under-developed healthcare infrastructures, their weak intellectual property laws and their unpredictable socio-political environments. But circumstances have changed dramatically. In fact, it is Australia which now faces the prospect of being overlooked

by global decision-makers because of a high-cost and highly burdened medical research system, an appreciating exchange rate and health workforce shortages.

To avoid this, stakeholders from across the research community in Australia must work together with Government to identify, develop and implement policies which help differentiate Australia from its competitors and help us better leverage our strengths in order to attract more investment.

We must work together to:

- promote a culture of collaboration and innovation throughout the country's healthcare system;
- rapidly implement reforms to create an efficient and cost-effective environment for medical research in Australia;
- increase support for basic research and commercialisation activities;
- implement globally competitive incentives to encourage private investment in research and development;
- implement incentives to encourage companies to invest in training and skills development;
- ensure the stability and predictability of Australia's reimbursement, regulatory and intellectual property systems; and
- ensure that the needs of the medical research community, including the medicines industry, are a key consideration in the design and future implementation of their national e-health plans.

If you have any questions about statements in this submission, please do not hesitate to contact me on 02 6122 8500.

Yours sincerely

Dr Brendan Shaw
Chief Executive

CONTENTS

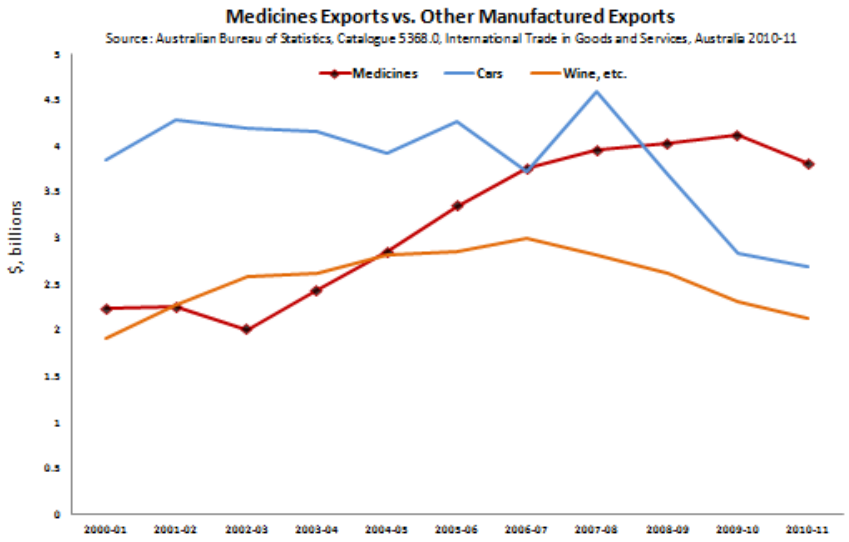
FIGURES

KEY FEATURES OF THE AUSTRALIAN MEDICINES INDUSTRY

- The Australian medicines industry is part of the global medicines industry which is currently worth around US$890 billion, and which is expected to be worth over $1 trillion by 2015.[1]

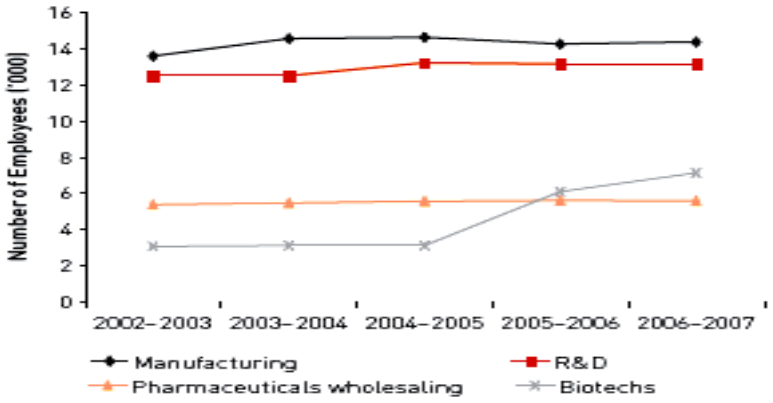
- The medicines industry is one of Australia's largest exporters of manufactured goods. As Figure 1 shows, it exports more by value than the Australian car and wine industries. Since 1990, exports of medicines have increased by more than 800%. Major markets for Australian medicinal exports include Asia (40%), southern Africa (20%) and Europe (16%).[2]

Figure 1



- The medicines industry in Australia employs over 40,000[3] exceptionally talented Australians, making it one of the largest employers of university graduates, especially science graduates, in Australia. The industry creates high-quality jobs, which builds high-value skills, helps retain skilled professionals in Australia and attracts outstanding talent from overseas. In the process, the industry is able to provide opportunities for career development in many professional areas, ranging from research and clinical sciences to marketing, information technology, manufacturing and health economics (see Figure 2 below).

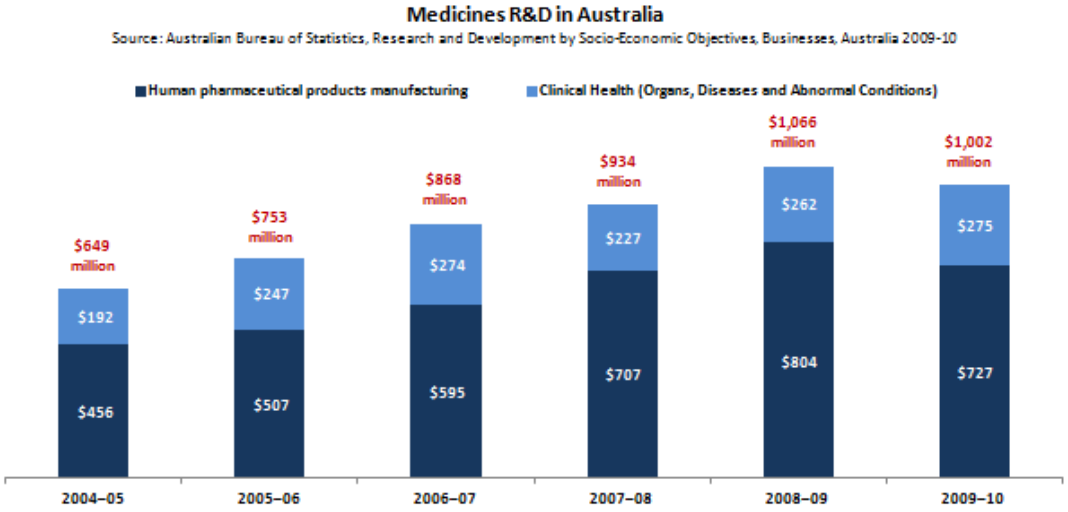
Figure 2: Breakdown of Employment in the Medicines Industry



[1] IMS Health, 2011, IMS Market Prognosis.
[2] Commonwealth Department of Foreign Affairs and Trade, 2011, STARS Database, based on ABS Cat No. 5368.0.
[3] Commonwealth of Australia, 2008, Pharmaceuticals Industry Strategy Group, Final Report.

- Since 2004, as Figure 3 shows, the Australian medicines industry has invested over $5 billion in research and development, including on over 4,500 clinical trials[4] in more than 30 therapeutic areas such as oncology and mental health.

Figure 3



[4] Therapeutic Goods Administration, 2012, Half-Yearly Performance Report, Clinical Trials (Medicines).

SUMMARY OF RECOMMENDATIONS IN THIS SUBMISSION

A. *Australian governments should not only (continue to) regard public and private investment in medical research as an investment in Australia's future, but also work with other stakeholders to actively promote a culture of collaboration and innovation in Australia's healthcare system by, for example, including research outputs as a key performance indicator for health providers and healthcare institutions in Australia.*

B. *Australian governments (including state and territory governments), academics, universities, hospitals, medical researchers, healthcare providers, patient groups and the medicines industry should work together to create an efficient and cost effective environment for medical research in Australia by, for example, urgently implementing the recommendations of the Clinical Trials Action Group.*

C. *Australian governments should provide greater support for both basic research as well as commercialisation activities by, for example, increasing funding for the National Health & Medical Research Council and expanding the role of Commercialisation Australia.*

D. *Australian governments should provide globally competitive incentives to encourage major investment by companies in research and development infrastructure by, for example, establishing a Strategic Co-Investment Fund, lowering Australia's corporate tax rate or raising the level of tax credits available to companies conducting medical research in Australia.*

E. *Australian governments should consider implementing incentives (such as tax breaks and/or grants) to encourage companies to invest in developing, educating and up skilling their employees.*

F.1 *Australian governments, the medicines industry and other stakeholders should work together to ensure the stability and predictability of Australia's reimbursement, regulatory and intellectual property systems.*

F.2 *Australian governments should reject calls to exclude biological materials from patentable subject matter.*

F.3 *The term of data exclusivity in Australia should be extended to harmonise an important element of Australian intellectual property system with international best practice.*

G. *Australian governments should ensure that the needs of the medical research community, including the medicines industry, are a key consideration in the design and future implementation of their national e-health plans.*

RESONSES TO THE TERMS OF REFERENCE AND RECOMMENDATIONS

1. The need for Australia to build and retain internationally competitive capacity across the research spectrum, from basic discovery through clinical translation to public health and health services research.

RESPONSE

Medicines Australia believes that it is essential for Australia to remain a competitive location for foreign and domestic investment in the full range of medical research activities, from basic discovery to clinical research to the delivery of innovative health services. Among its other benefits, this investment:

- supports high-skilled jobs across Australia, including around 13,000 medical research jobs in the medicines industry alone;
- underpins the long-term commercial viability of a growing and increasingly export-oriented Australian medicines industry;
- plays a vital role in improving Australia's healthcare system; and, above all,
- allows Australians to live healthier and more productive lives.

A 2008 report by Access Economics showed that for every dollar invested in medical research in Australia, Australians gain approximately $2.17 in health benefits in return. It added that between 1992 and 2005, public and private sources invested around $14 billion on medical research, which generated nearly $30 billion in health benefits for Australians over the same time period.[5] These findings were broadly supported by a separate investigation by Lateral Economics, which in 2011 found that by maintaining even current levels of investment in medical research, Australians could gain up to $150 billion in health benefits over the next 10 years.[6] As both reports show, it makes clear economic sense for Australian policy makers and the broader medical research community (including the medicines industry) to work together to ensure Australia remains a competitive location for foreign and domestic investment in medical research.

Separately, two recent analyses show that direct involvement by doctors in clinical research means best-practice treatments and procedures are quickly translated and adopted into everyday clinical practice. This benefits patients and improves health outcomes. According to one of these studies, published in 2008 in the *Archives of Internal Medicine*, "patients treated at hospitals that participate in [clinical research] have a lower mortality rate than patients treated in non-participating hospitals".[7] A second study, published in *The Lancet* in 2006, argued that "physicians who design and/or implement research studies translate the results of the most up to date medical literature more promptly and to a greater extent than physicians in routine clinical practice".[8]

While both of these studies based their conclusions on overseas data, local experience demonstrates that investment in medical research produces (roughly) the same benefits in

[5] Access Economics, 2008, *Exceptional Returns II: The Value of Investing in Health R&D in Australia*, report prepared for the Australian Society of Medical Research.
[6] Lateral Economics, 2010, *The Economic Value of Australia's Investment in Health and Medical Research: Reinforcing the Evidence for Exceptional Returns*, report prepared for Research Australia.
[7] Sumit R. Majumdar, et. al., 2008, Better Outcomes for Patients Treated at Hospitals That Participate in Clinical Trials, Archives of Internal Medicines, 168:6.
[8] S Claiborne Johnston, et. al., 2006, Effects of a US National Institutes of Health Programme of Clinical Trials on Public Health and Costs, The Lancet, 367.

Australia as well.[9] For example, recent clinical trials conducted in Australia gave Australian doctors first-in-class knowledge in the most effective utilisation of a drug called imitanib in the treatment of myelogenous leukaemia. It also gave them an opportunity to develop a molecular assay to more accurately measure an individual patient's response to the new therapy. This advancement, which was the direct result of Australian research, continues today to ensure that only those patients (around the world) who are likely to respond positively to the treatment receive the actual medicine.

The benefits to Australians of advances in health technologies cannot be underestimated. At 81.5 years[10], we enjoy one of the longest life expectancies in the world, with mortality and morbidity rates from all causes – according to the Australian Bureau of Statistics – dropping by around 50% over the last four decades.[11] In 1971, for example, around 900 Australian men and 550 Australian women died as a result of cardiovascular disease. In 2007, these numbers had declined to around 230 for both Australian men and women. A significant portion of these health gains can be directly attributed to the availability and use of innovative medicines, such as various types of statins.

Due to the introduction of novel vaccines, a massive reduction in the burden of some infectious diseases in this country in the last ten years demonstrates the value of ongoing medical research in a particularly compelling way. For example, between 1997 and 2007, the number of reported cases of measles, mumps and rubella in Australia declined by 72%, according to data collected by the National Notifiable Diseases Surveillance System. According to the same source, the number of reported cases of Heamophilus Influenza Type B dropped by over 95% between 1991 and 2007. Both these gains directly resulted from the introduction of novel vaccines in the late 1980s.[12]

In summary, investment in medical research delivers numerous social, economic and health benefits to Australians. For this reason, it is vital for Australia to remain a competitive location for such investment from all public and private sources.

RECOMMENDATION

A. *Australian governments should not only (continue to) regard public and private investment in medical research as an investment in Australia's future, but also work with other stakeholders to actively promote a culture of collaboration and innovation in Australia's healthcare system by, for example, including research outputs as a key performance indicator for health providers and healthcare institutions in Australia.*

Given the central role healthcare professionals and healthcare institutions play in facilitating and conducting medical research in Australia, future national reforms will be difficult at best, or even impossible, to implement without the explicit support of these groups. It is therefore crucial for the Government and other stakeholders to work together to promote a culture of research and innovation throughout Australia's healthcare system. This would ensure that research is viewed by all relevant parties as a core function of Australia's healthcare system rather than an extracurricular activity for some staff members.

[9] NSW Clinical Trials Business Development Centre, 2008, Value of Industry Sponsored Clinical Trials in Australia: Inaugural Survey of Investigator Perceptions of the Value of Industry Funded Clinical Research.
[10] Australian Institute of Health and Welfare, Australia's Health 2010.
[11] Australian Bureau of Statistics, 2009, Age-Standardised Death Rates (All Causes), Australia.
[12] Australia Institute of Health and Welfare, Australia's Health 2008.

One explicit method of promoting, and even institutionalising, a culture of innovation in Australia's healthcare system would be to make research output a key performance indicator for health providers and health care institutions in this country. In return, institutions and individual medical professionals who perform well against this criteria would not only attract a higher level of industry investment for sponsored and independent research, but their day-to-day clinical activities could attract a premium rate of reimbursement.

2. Current expenditure on, and support for, health and medical research in Australia by government at all levels, industry, non-government organisations and philanthropy, including relevant comparisons internationally.

3. Opportunities to improve coordination and leverage additional national and international support for Australian health and medical research through private sector support and philanthropy, and opportunities for more efficient use, administration and monitoring of investments and the health and economic returns; including relevant comparisons internationally.

4. The relationship between business and the research sector, including opportunities to improve Australia's capacity to capitalise on its investment in health and medical research through commercialisation and strategies for realising returns on Commonwealth investments in health and medical research where gains results from commercialisation.

5. Opportunities to improve national and international collaborations between education, research, clinical and other public health related sectors to support the rapid translation of research outcomes into improved health policies and practices.

The following section responds to elements of all of four of these terms of reference. The comments here should be considered in conjunction with the comments and recommendations by Research Australia and Association of Australian Medical Research Institutes.

RESPONSE

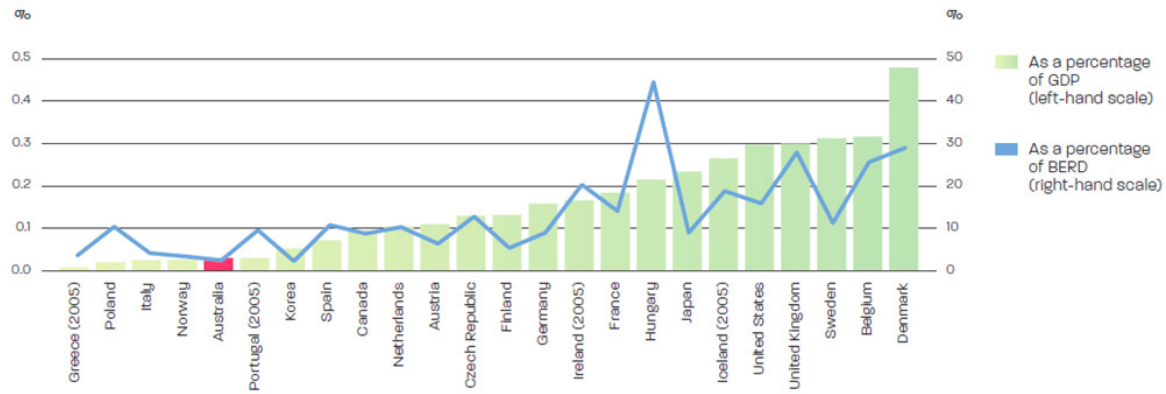
According to data published by the Australian Bureau of Statistics, the Australian medicines industry is the third largest investor in research and development – behind the financial services and mining industries – and the largest private investor in medical research in Australia.[13] In 2009-10 alone, it invested just over $1 billion on research and development, much of it on clinical trials (which is discussed in more detail below).

Globally, the medicines industry is one of the largest investors in research and development, with an annual investment of approximately $70 billion.[14] In some OECD countries, as Figure 4 shows, the medicines industry accounts for nearly a third (or more) of all business expenditure on research and development in those countries.[15] In addition, recent data from the European

[13] Australian Bureau of Statistics, 2009-10, Research and Experimental Development by Socio-Economic Objectives, Catalogue 8104.
[14] Pharmaceutical Research and Manufacturers of America, 2011, PhRMA Profile 2011.
[15] Organisation of Economic Cooperation and Development, 2009, Science, Technology and Industry Scorecard 2009.

Commission shows that the medicines industry accounts for between 35 and 45 percent of all business expenditure on research and development in Europe, North America and Japan.[16]

Figure 4: R&D in the pharmaceuticals industry as a percentage of GDP and BERD, 2006



In Australia, while a majority of the medicines industry's investment in research and development is on clinical research, or, more specifically, on clinical trials[17], it is nevertheless a valuable contributor to all stages of medical research (and product development).

A number of companies in the medicines industry have recently established multi-million dollar partnerships with academic research institutes for the purpose of researching, developing and commercialising new treatments in a variety of therapeutic areas.

Just this year, for example, Les Laboratoires Servier, which is a leading European pharmaceuticals company, announced that it would work with Monash University's Institute of Pharmaceutical Sciences (MIPS) to gain a better understanding of the role of G Protein-Coupled Receptors (GCPR) in human disease. This research could ultimately lead to new treatments for metabolic, cardiac, neurological and rheumatological disorders. Speaking about the collaboration, MIPS Director, Professor Bill Charman, said "We are delighted to partner with Servier to advance our research and to translate our GPCR-based drug discovery insights to design new therapeutic agents for major human diseases".[18]

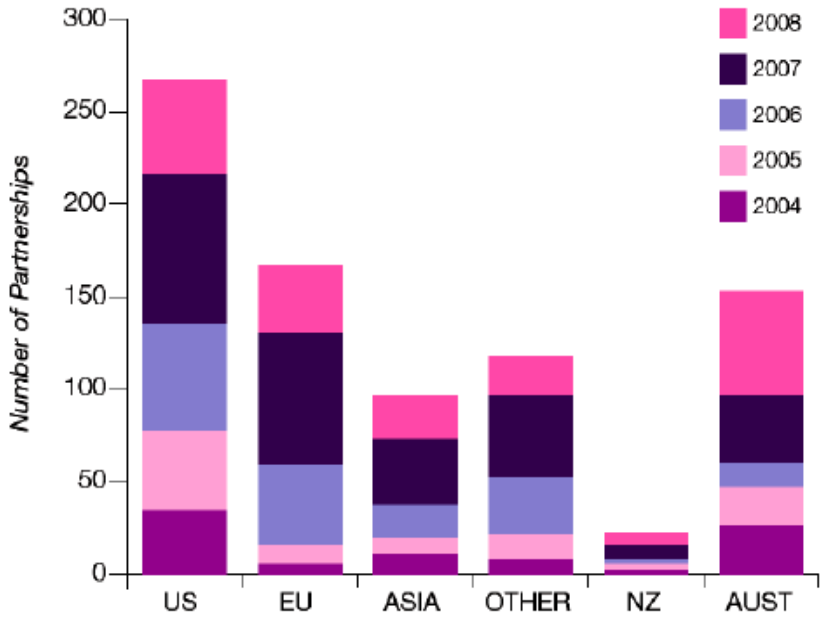
On the other end of the research continuum, MIPS has also used its expertise to partner with the London-based company GlaxoSmithKline, which is also among the largest pharmaceutical companies in the world, to "translate cutting-edge science into advanced manufacturing capabilities and next generation pharmaceutical products destined for the national and international markets".[19]

Separately, in 2010, the American-based pharmaceutical company Eli Lilly, which is also among the world's largest pharmaceutical companies, announced that it would invest $250 million in a

[16] European Commission, 2011, Monitoring Industrial Research: The 2011 EU Industrial R&D Investment Scoreboard, 2008-09.
[17] For example, see: Medicines Australia, 2010, Winds of Change: Report on the 2009 Medicines Australia Economic Survey.
[18] Monash Institute of Pharmaceutical Sciences press release, 2012, Monas Institute of Pharmaceutical Sciences (MIPS) and Servier Laboratories to Collaborate on G-Protein Couples Receptors.
[19] Monash Institute of Pharmaceutical Sciences press release, 2009, Monash Institute of Pharmaceutical Sciences Partners (MIPS) With GlaxoSmithKline With State Government Support.

venture capital fund to back the expansion and development of the biotechnology industry in Queensland. The State Government said that it would provide $25 million in additional funding to support this collaboration, with the then State Premier Anna Bligh stating that "scientists and researchers in Queensland will now be able to secure even more of the $5 trillion [global] intellectual property rights market ".[20]

Figure 5: Global Bio-Pharma Partnerships – 2004 - 2008



Such research and commercialisation partnerships between global pharmaceutical companies and Australian biotechnology companies are an increasingly important feature of the business landscape in Australia. In fact, as Figure 5 shows[21], between 2004 and 2008, Australian bio-pharmaceutical companies formed nearly as many global partnerships as bio-pharmaceutical companies based in the whole of the European Union (a region which accounts for nearly a third of the global market for medicines, as opposed to Australia which accounts for around 1%). These partnerships are especially important given how often significant gains from basic research and proof-of-concept activities have been lost in the past because start-ups and small firms in Australia have inadequate access to advice and funding from multinational companies (and Government). The ever increasing number and size of commercial partnerships means that, in the future, a greater number of Australian discoveries could eventually lead to breakthrough medicines that are marketed all over the world.

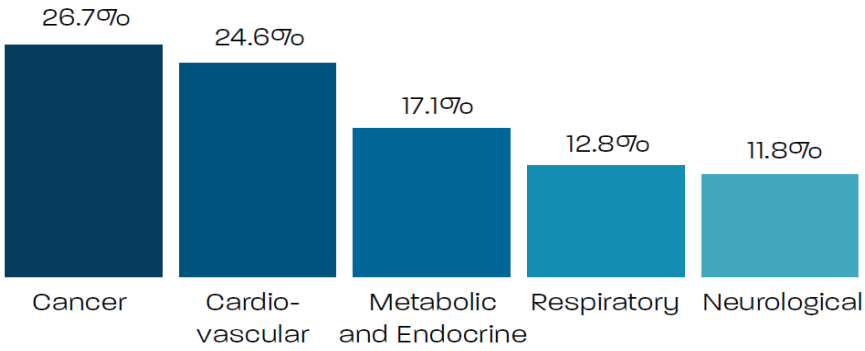
CLINICAL TRIALS

As already noted, a majority of the medicines industry's investment in research and development in Australia is on clinical trials, which are an indispensible and, in many cases, the most expensive component of the drug development process. Since 2004, the industry has initiated over 4,500 clinical trials in Australia[22] in more than 30 therapeutic areas[23], such as

[20] Queensland Government press release, 2010, Australian-First: $250m Fund to Drive Innovation Out of Queensland.
[21] Commonwealth Department of Innovation, Industry, Science, Research and Tertiary Education, 2010, Biotech Business Indicators, Q 1.
[22] Therapeutic Goods Administration, 2012, Half-Yearly Performance Report, Clinical Trials (Medicines).
[23] NSW Clinical Trials Business Development Centre, 2008, Value of Industry Sponsored Clinical Trials in Australia: Inaugural Survey of Investigator Perceptions of the Value of Industry Funded Clinical Research.

oncology and mental health (Figure 6). Every year, more than 18,000 Australians participate in clinical trials conducted in Australia.[24]

Figure 6: Top 5 Areas of Clinical Trial Activity in Australia

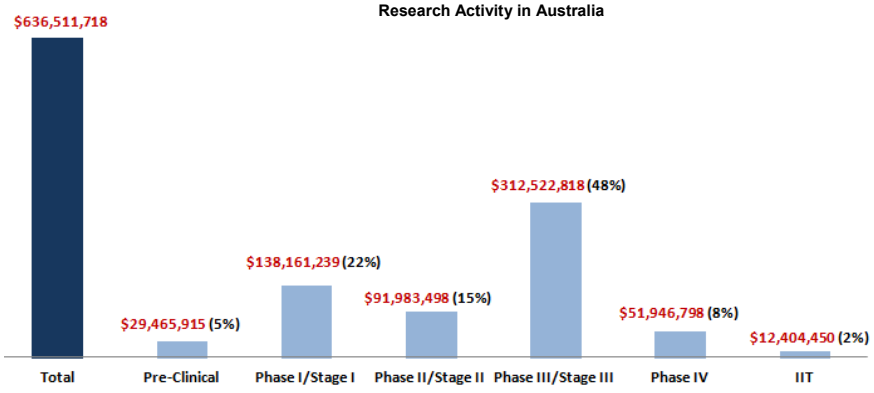


Clinical trials are important not only for the massive investment they bring to Australia, but also for the role they play in improving Australia's healthcare system. Among other things, clinical trials provide early and often free access to new healthcare technologies, which, according to the Government's own estimates, saves Australian taxpayers around $100 million each year in hospital and PBS costs.[25]

In a recent survey of privately-funded clinical research activity in Australia, 53 companies reported a total investment of almost $650 million in 2010. While the response rate to the survey was only 50%, it nevertheless captured a vast majority of the (private) investment in clinical trials in Australia.[26]

As Figure 7, Phase III clinical trials – individually – were by far the largest component of clinical research activity in Australia in 2010; 48% in terms of investment (and 39% in terms of the number of studies – graph not included). However, early stage research (i.e., pre-clinical, Phase I and Phase II clinical trials) were major areas of investment as well; collectively, early stage clinical research accounted for 42% of the total investment. This is important because early stage research has been repeatedly shown to have a higher potential to deliver spill over benefits to the Australian economy, compared to late stage clinical research.[27]

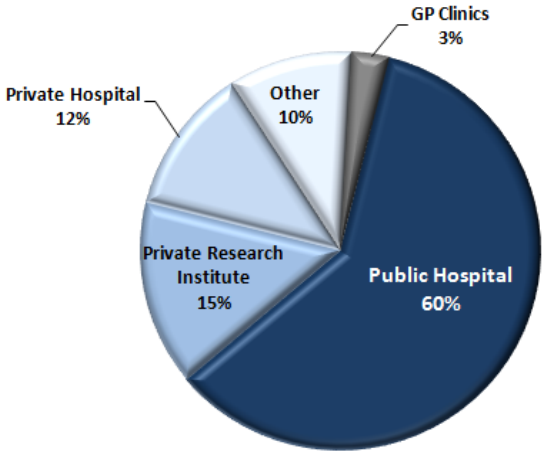
Figure 7: Reported Expenditure – 2011 Survey of Privately Funded Clinical Research Activity in Australia



[24] Pharmaceuticals Industry Council, 2010, 2nd Benchmarking Survey of Privately Funded Clinical Research Activity in Australia.
[25] Senator the Hon Kim Carr, 2011, Speech at the Medicines Australia Parliament Dinner on 2 March 2011.
[26] Commonwealth Department of Innovation, Industry, Science, Research and Tertiary Education and the Pharmaceuticals Industry Council, 2012, 2011 Survey of Privately Funded Clinical Research Activity in Australia.
[27] Productivity Commission, 2003, Evaluation of the Pharmaceutical Industry Investment Program.

Data from this survey also showed that, in a strictly monetary sense, one of the main beneficiaries in Australia of private investment in clinical research are public hospitals (Figure 8). Of the total reported activity, 60% was conducted in public hospitals across Australia.

Figure 8: Research Location – 2011 Survey of Privately Funded Clinical Research Activity in Australia



This was another important finding as private investment is not only an additional funding source for Australia's public health system, but also a means of subsidising the delivery of healthcare to Australian patients. The higher the investment in the future, the higher rate of additional funding, the higher the subsidy and, ultimately, the higher the benefit to Australian patients.

In recognition of the importance of maintaining private investment in clinical research, the Australian Government in 2009 established the Clinical Trials Action Group to "help cement Australia's position as a good place to conduct clinical [research]".[28]

In its final report, the Action Group made over 20 recommendations, aimed mostly at improving patient recruitment and making the process of initiating and conducting clinical trials in Australia significantly more efficient and cost-effective. In their foreword to the final report, then Ministers for Health & Ageing, the Hon Nicola Roxon MP, and Innovation & Industry, Senator the Hon Kim Carr, wrote that the Australian Government had accepted all of the Group's recommendations, and that "the relevant Government departments and agencies will work together to implement them [by July 2011]". They said that doing so would "ensure that Australian patients receive high quality, better coordinated and sustainable health care over the coming decades".[29]

Unfortunately, more than 12 months after the report's release, many of the Action Group's recommendations have not been implemented. This issue is discussed in more detail below.

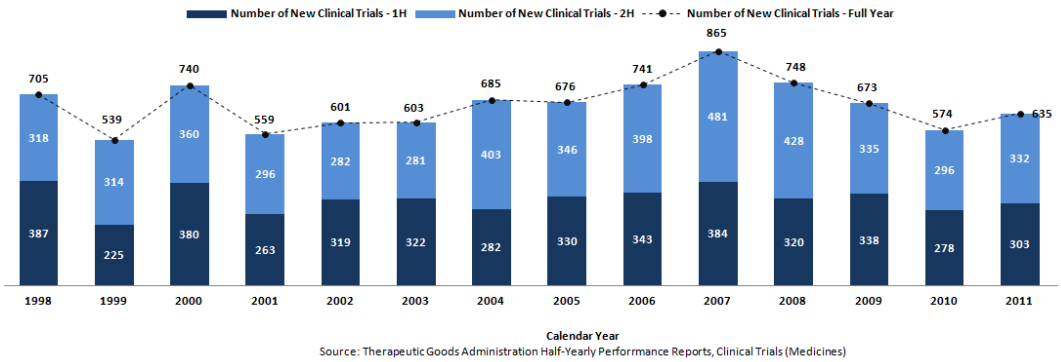
RECOMMENDATIONS

B. *Australian governments (including state and territory governments), academics, universities, hospitals, medical researchers, healthcare providers, patient groups and the medicines industry should work together to create an efficient and cost effective environment for medical research in Australia by, for example, urgently implementing the recommendations of the Clinical Trials Action Group.*

[28] Commonwealth of Australia, 2011, Clinically Competitive: Boosting the Business of Clinical Trials in Australia.
[29] Ibid.

As noted already, clinical trials are a vital source of investment and health benefits for Australia. However, while there has been a small recent recovery, data from the Therapeutic Goods Administration shows that the numbers of new clinical trials in Australia have declined by 34% percent between 2008 and 2010 (Figure 9).

Figure 9
Number of New Clinical Trials



Source: Therapeutic Goods Administration Half-Yearly Performance Reports, Clinical Trials (Medicines)

In its final report, the Clinical Trials Action Group made over 20 recommendations, aimed mostly at improving patient recruitment and making the process of initiating and conducting clinical trials in Australia significantly more efficient and cost-effective.

Among these recommendations, the most urgent called for the:

- *implementation of a nationally harmonised system of ethics review for multi-centre clinical trials;*

  Slow start up times are routinely identified by clinical trial sponsors in Australia as the most important reason why Australia is losing its competitive edge against other countries. In a 2010 industry survey, more than 30% of respondents reported that it took them between 4 and 6 months just to initiate a clinical trial.[30] This not only causes delays in patient access to clinical trials (and treatments), it also delays the overall development of new medicines and diverts a company's financial resources away from actual R&D to meeting inefficient regulatory requirements.

- *creation of a table of standard costs associated with conducting clinical trials in Australia, which is based on the principles of cost recovery and efficient delivery of services*.

  Australia is among the most expensive countries in the world in which to conduct clinical trials. The situation is made worse due to the significant variability in what individual research sites charge for performing virtually identical tasks. A recent comparison of site start up fees across 22 research sites for an actual commercially sponsored study clearly demonstrated the variability in start up costs between sites for the same start up activities. In this study, individual site start up fees ranged from $4,900 to $41,418, with an average

[30] Pharmaceuticals Industry Council, 2010, 2nd Benchmarking Survey of Privately Funded Clinical Research Activity in Australia.

cost of $19,887 and a total start up cost of $437,499.[31] This cost was incurred before a single patient was enrolled in the study.

- *creation of a Government website to raise consumer awareness of clinical trials in Australia.*

In Australia no single entity is responsible for the conduct and dissemination of information regarding clinical trials. Access to the necessary information requires a user, be they consumer, patient advocate, researcher or industry representative, to search numerous websites and/or databases for studies that are being conducted in Australia and their status. Often the required information is not self-evident and may require extensive internet searches, a sound knowledge of the clinical research industry and a thorough knowledge of their disease and treatment options. To a potential clinical trial patient, understanding the option of joining a clinical trial, increasing their disease awareness and then searching for suitable clinical trials and locating the required information is, at best, difficult.

Medicines Australia strongly supports the urgent implementation of these recommendations.

Separately, we also strongly support the creation of a national clinical trials office. While the last of these points was not a CTAG recommendation, Medicines Australia strongly believes that a national clinical trials office will provide structure and clear national leadership aimed at continually improving Australia's global competitiveness in clinical trials across a complex regulatory and health environment. It would also play a key role in promoting Australia internationally as a destination for investment in clinical trials. Currently, the responsibility of regulating and overseeing clinical trials is given to a wide variety of state and federal government agencies. Because of this diffusion of responsibility, no single agency is ultimately responsible for making sure that Australia remains a competitive location for clinical trials investment.

Translational and Commercialisation Issues

C. *Australian governments should provide greater support for both basic research as well as commercialisation activities by, for example, increasing funding for the National Health & Medical Research Council and expanding the role of Commercialisation Australia.*

Medicines Australia believes that there is significant room for improvement in Australia's commercialisation culture. Significant gains from basic research and proof-of-concept activities are still being frequently lost because start ups and small firms have inadequate access to advice and funding from multinational companies and the Government. Commercialisation Australia provides valuable support in this regard, but grants so far have been too small to facilitate large-scale commercialisation projects. Moreover, funding from multinational companies has been limited because Australia lacks local mechanisms to identify promising research.

D. *Australian governments should provide globally competitive incentives to encourage major investment by companies in research and development infrastructure by, for example, establishing a Strategic Co-Investment Fund, lowering Australia's corporate tax rate or raising the level of tax credits available to companies conducting medical research in Australia.*

In 1988, when the Australian medicines industry was facing massive disinvestment and an escalating deficit in the pharmaceutical balance of trade, the Australian Government introduced

[31] Unpublished data.

the Factor F scheme, which ran from 1988 to 1999. Under Factor F, which encouraged companies to make significant manufacturing and research and development investments in Australia through notional price increases for products supplied through the Pharmaceutical Benefits Scheme, the industry's core capacity to conduct research and development (and manufacture high-value therapeutic products for domestic and export markets) skyrocketed. Over the 10 years of the program, the industry created more than 1000 new jobs and achieved a cumulative increase of over $600 million in additional R&D expenditure (and approximately $4 billion in production value-add).[32]

Then in 1999, the Australian Government announced the Pharmaceuticals Industry Investment Program (PIIP) as a follow-up to Factor F. This 5-year program, with up to $300 million in available funding, operated from 1999 to 2004. In its 2003 review of the program, the Productivity Commission concluded that "PIIP has been effective in stimulating R&D and production value-add. It has also had broader benefits for the capabilities of the industry, for example, by shifting R&D to more complex areas".[33]

Past collaborations between industry and successive Australian governments have worked well, both for the industry as well as for Australia. The rapid growth of the industry between 1988 and 2008 (when the last such program, P3, concluded) can be directly attributed to Factor F, PIIP and P3. These programs represented an ongoing and productive partnership between industry and Australian governments to stimulate growth in one of Australia's most dynamic and innovative industries. Given the immense benefits to Australia, as demonstrated by the growth in jobs, exports and research output, a similar form of partnership should be re-established.

In 2008, the Pharmaceuticals Industry Strategy Group, which brought together more than a dozen industry leaders with a view to create a plan to secure the biopharmaceutical industry's future in Australia, recommended that the Government establish a Strategic Co-Investment Fund. Under the proposal, the Government would contribute up to 20% of the cost of a new manufacturing or research infrastructure project, but only if the project is judged by an independent committee to have the potential to provide "significant and substantial benefits to Australia".[34]

Unfortunately, the Strategic Co-Investment Fund has not yet been established, despite the Pharmaceuticals Industry Strategy Group's final report clearly demonstrating a strong business case for doing so.

Medicines Australia believes that a Government initiative such as the Strategic Co-Investment Fund need not be a measure specific to the biopharmaceuticals industry. Indeed, a program under which companies operating in Australia in various knowledge-intensive industries (such as the ICT, aerospace and renewable energy industries) compete with companies operating in the pharmaceuticals industry for investment funds could be an extremely effective way of promoting investments by industries which will be crucial to Australia's future prosperity without having to "pick winners".

[32] Industry Commission, 1996, The Pharmaceutical Industry in Australia.
[33] Productivity Commission, 2003, Evaluation of the Pharmaceutical Industry Investment Program.
[34] Commonwealth of Australia, 2008, Pharmaceuticals Industry Strategy Group, Final Report.

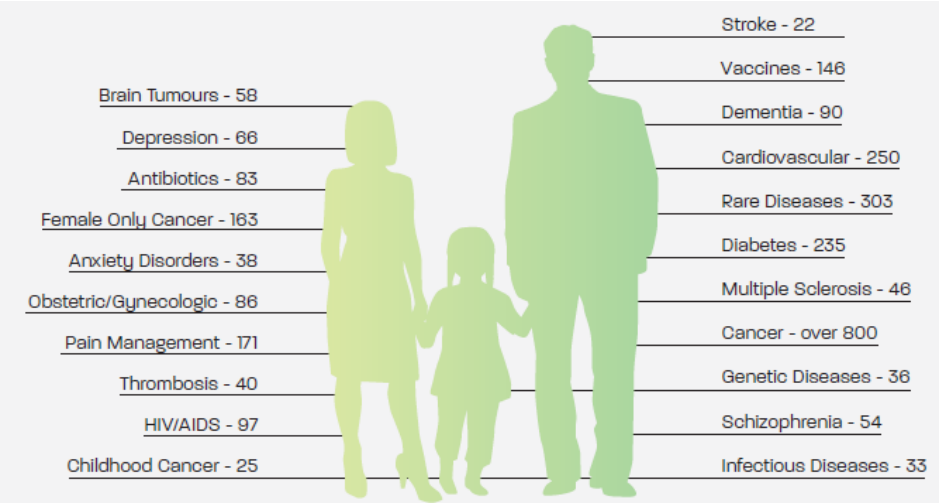
6. Likely future developments in health and medical research, both in Australia and internationally.

7. The degree of alignment between Australia's health and medical research activities and the determinants of good health, the nation's burden of disease profile and national health profile.

RESPONSE

As described already, innovation in medicines provides new treatment options for society. People with various illnesses and conditions enjoy the benefits of this innovation in the form of new medicines and vaccines to treat or prevent illnesses, in many cases for conditions for which there had been no effective treatment available before.

Figure 10: Medicines Under Development



As Figure 10 shows[35], currently there are nearly 3,000 medicines and vaccines in development by the global medicines industry to help people live longer and more productive lives. Among these are hundreds of medicines that meet Australia's current national health priorities. For example, there are more than 800 medicines in development to treat various forms of cancer, around 300 to treat rare diseases such as Addison's disease and cystic fibrosis, over 250 to treat cardiovascular disease and nearly as many to treat diabetes. Australia is playing its part in this global effort not only by hosting clinical trials for many of these new medicines but also by making significant contributions to an understanding of human disease through basic research.

BIOLOGICAL MEDICINES & VACCINES

Biological medicines, as opposed to "small molecule medicines", represent the cutting edge of healthcare innovation. They have already revolutionised the field, and in time biological medicines are likely to deliver the most effective means of treating a variety of illnesses and disabilities.[36] Dozens of human-use biological medicines have been approved since 1990, and more than 400 are currently under development globally, targeting diseases such as cancer, AIDS, arthritis, Alzheimer's and Parkinson's.[37]

[35] Pharmaceutical Research and Manufacturers of America, 2011, PhRMA Profile 2011.
[36] DK Robinson and N Sethuraman, 2010, How Innovative Technology Is Moving Biologics Into the 21st Century, Nature, Clinical Pharmacology & Therapeutics, 87:3.
[37] Ibid.

Between 1998 and 2008 alone (Figure 11), at least 28 new medicines (whose active ingredients are made up of structurally complex biological materials) for diseases ranging from breast cancer to diabetes and heart disease were listed on the PBS. In addition, 19 vaccines such as Prevenar® and Priorix® (which also contain active ingredients made up of complex biological materials), to prevent a total of 16 communicable disease such as pneumococcal infections and measles, have been made available through Australia's National Immunisation Program. In 2011, some half a million Australians were treated using these medicines and vaccines.[38]

Figure 11: Examples of Biological Medicines Listed on the Pharmaceutical Benefits Scheme Between 1998 and 2008

Major Indications[39]	**Compound Name**	**Brand Name**
rheumatoid arthritis	Anakinra	Kineret®
rheumatoid arthritis	Adalimumab	Humira®
Diabetes mellitus	Insulin aspart	NovoRapid®
multiple sclerosis	Natalizumab	Tysabri®
rheumatoid arthritis	Abatacept	Orencia®
Anticoagulant	Bivalirudin	Angiomax®
fertility treatment	Choriogonadotropin α	Ovidrel®
severe sepsis	Drotrecogin alfa	Xigris®
osteoporosis	Teriparatide	Forteo®
cardiac ischemia	Eptifibatide	Integrilin®
rheumatoid arthritis	Etanercept	Enbrel®
prostate cancer	Triptorelin embonate	Diphereline®
multiple sclerosis	Glatiramer acetate	Copaxone®
Crohn's Disease	Infliximab	Remicade®
anaemia	Epoetin alfa	Eprex 2000®
colorectal cancer	Cetuximab	Erbitux®
macular degeneration	Ranibizumab	Lucentis®
neutropenia	Pegfilgrastim	Neulasta®
hepatitis C	Peginterferon alfa-2b	PEG-Intron®
HIV	Enfuvirtide	Fuzeon®
leukaemia	Rituximab	Mabthera®
myocardial infarction	Tenecteplase	Metalyse®
thyroid cancer	Thyrotropin alfa	Thyrogen®
breast cancer	Trastuzumab	Herceptin®

[38] Internal estimates.

[39] Nearly all of the medicines listed in this table are used to treat multiple conditions.

8. Strategies to attract, develop and retain a skilled research workforce which is capable of meeting future challenges and opportunities.

RESPONSE

Growth in the Australian medicines industry is being hampered by the persistent shortage of skilled workers. The workforce needs of the industry were the subject of a detailed study[40] in 2008 by the Pharmaceuticals Education Council (PEC), which brought together both industry representatives and senior academics from Australian universities.

The PEC found that there is a considerable shortage of specific skills required not just by the medicines industry but all knowledge-intensive industries in Australia. The report identified gaps across the value chain, and especially noted that many recent university graduates lack basic research, project management, clinical trial design, interpersonal, marketing and negotiating skills, all of which are critical to the business of bringing new products to market.

These findings were broadly supported by a Medicines Australia survey which found that Australian bio-pharmaceutical companies have had to import labour to meet shortages in several key areas such as clinical trial management and business development.

RECOMMENDATION

E. Australian governments should implement incentives (such as tax breaks and/or grants) to encourage companies to invest in developing, educating and up skilling their employees.

Unfortunately, given the already high cost of doing business in Australia, it is difficult for companies to invest in up-skilling their workforce. As such, incentives such as tax breaks and/or grants would not only allow companies to train their workforce but, in doing so, also add to Australia's general pool of skilled labour.

9. Ways in which health and medical research interacts, and should interact, with other Government health policies and programs; including health technology assessments and the pharmaceutical and medical services assessment processes.

RESPONSE

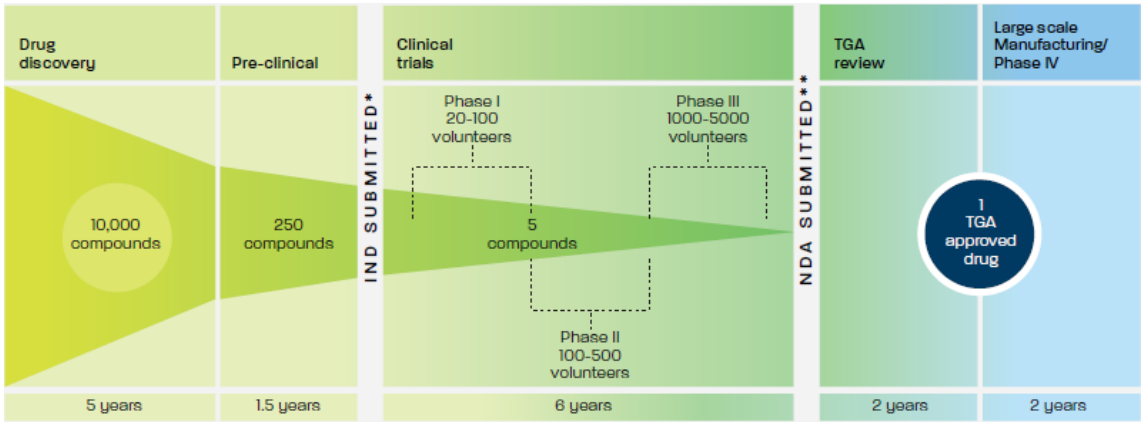
Medicines Australia strongly believes that stable, predictable and efficient pricing, regulatory and intellectual property systems are essential to ensuring ongoing investment in Australia by the medicines industry.

As shown in Figure 12, the development process is expensive, lengthy and characterised by an unusually high level of risk relative to other industries.[41] On average, the cost of bringing a new medicine to market is approximately US$1.2 billion, and it can take between 12 and 15 years to complete the process.[42] As this research and development pipeline is funded almost exclusively by returns on existing medicines, it is not surprising the company decisions about bringing new

[40] Pharmaceuticals Education Council, 2009, Report on Skills Gaps in the Pharmaceutical and Biopharmaceuticals Industries in Australia.
[41] Pharmaceutical Research and Manufacturers of America, 2011, PhRMA Profile 2011.
[42] J DiMasi and H Grabowski, 2007, The Cost of Biopharmaceutical R&D: Is Biotech Different?, Managerial and Decision Economics, 28.

medicines to Australia, as well ongoing investment in local research and development, are directly affected by industry confidence in Australia's reimbursement, regulatory and intellectual property systems.

Figure 12: Drug Development – From Discovery to Market



PHARMACEUTICAL BENEFITS SCHEME

For over 60 years, Australians have relied on the PBS to gain affordable access to the fruits of the latest medical research in the form of new therapeutic products.

Public expenditure on the PBS should be viewed by governments as an investment that helps:

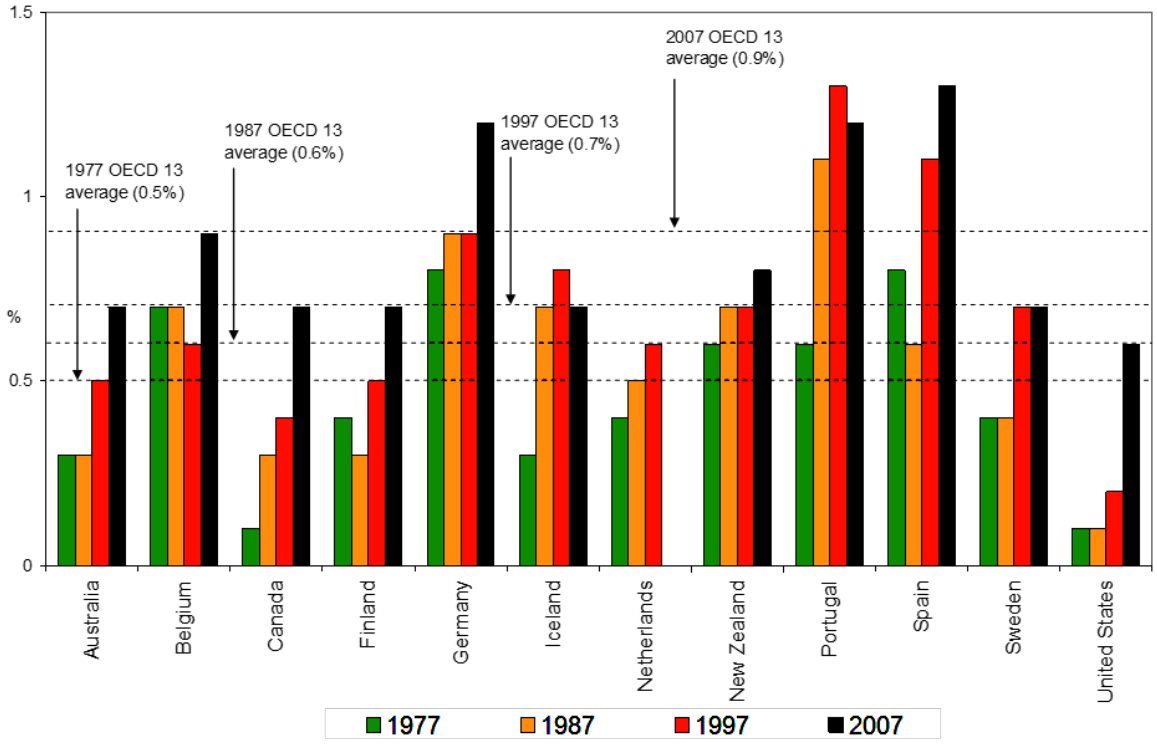
- protect the health and wellbeing of Australians;
- cost-effectively manage the healthcare needs of an ageing population;
- enhance productivity and workforce participation; and
- maintain a viable and responsible medicines industry in Australia.

Moreover, as Figure 13 shows, public expenditure in Australia on medicines as a share of gross domestic product remains very low by OECD standards.[43] This means not only that Australians are getting good value for money when it comes to their health and wellbeing but also that a reasonable rate of growth in public expenditure in the future is sustainable (and in fact necessary as an important driver of future investment in medical research[44]).

[43] Organisation of Economic Cooperation and Development, 2008, Public Expenditure on Pharmaceutical and Medical Non-Durables as Percentage of GDP.

[44] K Chalkidou, 2010, The (Possible) Impact of Comparative Effectiveness Research on Pharmaceutical Industry Decision Making, Nature, Clinical Pharmacology & Therapeutics, 87:3; and, Hans Friederiszick, et. al., 2009, An Economic Assessment of the Relationship Between Price Regulation and Incentives to Innovate in the Pharmaceutical Industry, White Paper No. 109-03, European School of Management and Technology.

Figure 13: Public Expenditure on Pharmaceuticals and Non-Durables in OECD Nations as a % of GDP



INTELLECTUAL PROPERTY

As noted above, the process of bringing new medicines to the market involves an extraordinary degree of risk.[45] Only a small portion of "promising research" yields safe and effective products, of which only a fraction are profitable enough to make the initial investment financially and materially worthwhile. On average, the cost of bringing a new medicine to market is approximately US$1.2 billion, and it can take between 12 and 15 years to complete the process.

By guaranteeing a clearly defined period of market exclusivity, different forms intellectual property rights such as patents and data exclusivity act to mitigate the extraordinary risk of bringing new medicines to market, making it significantly more likely for private companies to continue to invest in medical research.

Medicines Australia welcomes the recent passing of the *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011* legislation by the Australian Parliament. Once fully implemented, this legislation will enhance Australia's patent system, which is already among the strongest in the world. Among its other achievements, the Bill introduces an explicit research use exemption, which will directly address concerns among certain stakeholders that patents have the potential to stifle scientific research. An explicit research-use exemption will make it absolutely clear that scientists are free to conduct research on patented inventions, so long as it is for the purpose of investigating the patented invention and not their intention to infringe valid patents by selling or inappropriately using these inventions without the inventors' permission.

[45] J DiMasi, et. al., 2010, Trends in Risks Associated With New Drug Development: Success Rates For Investigational Drugs, Nature, Clinical Pharmacology & Therapeutics, 87:3

This legislation also includes changes to harmonise Australian patent law with American and European patent laws. Medicines Australia strongly believes that the Australian Government should now focus on harmonising other elements of Australia's intellectual property system, such as the term of data exclusivity, with international best practice. Currently, Australia's data exclusivity system is one of the weakest in the developed world. This issue is discussed in more detail below.

RECOMMENDATIONS

F.1 Australian governments, the medicines industry and other stakeholders should work together to ensure the stability and predictability of Australia's reimbursement, regulatory and intellectual property system.

For over 60 years the pharmaceuticals industry in Australia has worked in partnership with Government to ensure that Australian patients, through the Pharmaceutical Benefits Scheme, have access to safe and effective medicines when they need them, regardless of their ability to pay for these medicines.

Throughout this time, the pharmaceutical industry has repeatedly demonstrated its commitment to the PBS's sustainability. This is best demonstrated by the fact that the pharmaceuticals industry has been an active and willing participant in periodic negotiations with the Government to ensure the PBS's long-term viability.

Most recently, in 2010 Medicines Australia and the Australian Government signed a Memorandum of Understanding to deliver ongoing benefits to Australian consumers through the availability of cheaper medicines and faster PBS listings. Under the agreement, which was built on the principles of the 2007 PBS reform package, Medicines Australia members companies guaranteed price reductions for medicines on the PBS that will save Australian taxpayers $1.9 billion over five years. In return, the Government promised a stable and predictable operating environment.

Medicines Australia is absolutely committed to regular dialogue with Australian governments to ensure the PBS remains sustainable, thus eliminating or at least minimising the need for governments to take unilateral action that may endanger the biopharmaceutical industry's long term viability in Australia.

There is no doubt that decision making processes for regulation and reimbursement of medicines can have an impact on the investment decisions of companies about medical research. Companies' attitudes to investment in medical research in a particular country can be affected by the regulatory and reimbursement environment in that country. Rather like the findings of innovation theory which suggests that discriminating customers who value new technology are important for driving innovation, reimbursement agencies' valuation of innovation can have an impact on the investment in research and innovation done in a country. For example, if a company does not think a medicine is likely to be listed on the PBS, or would take a long time given the value proposition required to be communicated, it may consider it unethical to conduct clinical trials on a medicine it thinks is unlikely to be listed any time soon.

Similarly, companies do read signals from reimbursement agencies about how they value the degree of innovation in a medicine and if an agency or country develops a reputation for not valuing innovation sufficiently, it can have an adverse impact on companies' willingness to invest in medical research. New Zealand is a case in point where the medicines industry has more or

less abandoned such investment driven in large part by the restrictive pricing policies in that country that have effectively delayed and devalued the adoption of new medical technologies.

F.2 Australian governments should reject calls to exclude biological materials from patentable subject matter.

As discussed above, new developments in healthcare are increasingly dependent on significant advances in gene- and protein-based technologies. Constraining the ability of individuals and companies to patent biological materials, despite fulfilling all other requirements for patentability, will unquestionably harm both investment in R&D and [consequently] patient access to new and more effective treatments and diagnostic tests. At least four Government inquiries including two by the Australian Parliament have come to the same conclusion.

Most recently, on 22 September the Senate Legal & Constitutional Affairs Committee released a report recommending that Parliament reject a Private Members' Bill seeking to ban patents on biological materials. The bipartisan report, which quoted Medicines Australia's positions extensively, supported our position that imposing such a ban would harm patients, researchers and the pharmaceuticals industry in Australia.[46]

Following this report, the Australian Government also responded to recommendations by three other past inquiries into the validity of patents on genetic and biological materials. Importantly, the Government's response rejected calls to ban such patents and noted that its broader patent reform agenda would resolve many of the issues raised in the past by critics of "gene patents".[47]

Medicines Australia strongly rejects any suggestion that biological materials should be excluded from patentable subject matter. As in other fields of technology, we strongly believe that the question of patentability must be left to the Commissioner of Patents, the Australian legal system, and ultimately to the World Trade Organisation (whose members are required not to distinguish between fields of technology when establishing standards for patentable subject matter).

F.3 The term of data exclusivity in Australia should be extended to harmonise an important element of Australian intellectual property system with international best practice.

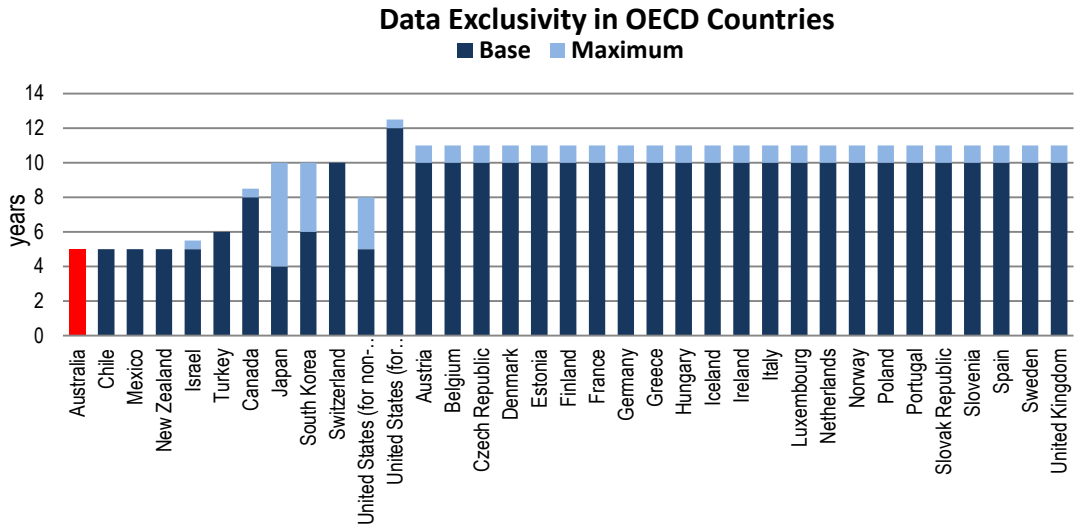
Medicines Australia strongly believes that the Australian Government should focus on harmonising all elements of Australia's intellectual property system, such as the term of data exclusivity, with international best practice, just as it has already with the patent system.

[46] Australian Senate, Legal and Constitutional Affairs Legislation Committee, 2011, Report on the *Patent Amendment (Human Genes and Biological Materials) Bill* 2010.

[47] Commonwealth of Australia, 2011, The Australian Government's Combined Response to the Senate Community Affairs References Committee's Inquiry Into Gene Patents (2008-2010), the Advisory Council on Intellectual Property's Report on Patentable Subject Matter (2008-2011) and the Australian Law Reform Commission's Report # 99, 2004, Genes and Ingenuity: Gene Patenting and Human Health.

As Figure 14 shows, Australia's data exclusivity system, which is a crucial indicator of the strength of a country's intellectual property system, is one of the weakest in the developed world. Medicines Australia strongly believes that the term of data exclusivity in Australia should be extended to bring it into line with leading OECD nations.

Figure 14



Extending the term of data exclusivity will help bring the Australian intellectual property system in line with leading OECD nations. This will improve Australia's attractiveness as a destination for foreign investment by global biopharmaceutical companies. It will also support the local biotechnology sector, which has only recently begun entering the international market with its own products such as Gardasil®, Relenza®, Axiron®, and a suite of groundbreaking products based on stem cell technology being developed by Victorian company Mesoblast. Moreover, as industry leaders note, extending the data exclusivity would send a powerful signal to the international business community that Australia values innovation as much as any developed country in the world, and that it is prepared to take the necessary steps to attract its fair share of the global investment pie.

10. Ways in which the Commonwealth's e-health reforms can be leveraged to improve research and translation opportunities, including the availability, linkage and quality of data.

RESPONSE

Australian geography is one of the many challenges faced by both clinical researchers as well as patients and health volunteers wanting to participate in clinical trials.

From the researchers' point of view, trial participants are sometimes scattered across multiple centres, and trial monitors currently have to expend enormous amounts of time and money in travelling to review patient medical records to verify study data.

From the patients' and volunteers' point of view, Australians in remote and regional areas (especially) have little opportunity to participate in clinical trials since researchers (and sponsors) rarely use regional hospitals and healthcare centres to conduct clinical trials due to travel requirements and other expenses.

Building a comprehensive and integrated e-health system in Australia, which, among other things, responds to specific research requirements such as allowing trial monitors to remotely and electronically access health records of patients involved in clinical trials, would dramatically boost research productivity, increase recruitment and give Australians in regional and remote areas access to the benefits of participating in clinical trials.

RECOMMENDATION

F. Australian governments should ensure that the needs of the medical research community, including the medicines industry, are a key consideration in the design and future implementation of their national e-health plans.

11. Opportunities for Australia's health and medical research activities to assist in combating some of the major barriers to improved health globally, especially in the developing world.

RESPONSE

The global medicines industry is already at the forefront of the effort to bring life saving medicines to patients in less developed countries around the world, especially to the poorest people in the world's least developed countries. Between 2000 and 2010 alone, the medicines industry invested over $11 billion in health programs in some of the world's least developed countries, and donated around 2 billion doses of vaccines and medicines for infectious and chronic diseases.

As an important partner in the global healthcare continuum, Australia plays a vital role in researching, developing and distributing products to treat illnesses in some of the world's poorest countries, including some which are Australia's neighbours. For example, a consortium of pharmaceutical companies, including Gilead Sciences, Boehringer Ingelheim, Merck Sharp & Dohme, Janssen, BristolMyersSquibb, Abbott, Roche, Pfizer, GlaxoSmithKline and ViiV Healthcare established a program in 2003 to work with non-governmental organisations to combat the rise of HIV/AIDS in Papua New Guinea (PNG). Through the consortium more than 50,000 people in PNG have accessed professional counselling and 3000 are currently receiving active treatment for HIV/AIDS. Among its other benefits, this collaboration has provided workshops for hundreds of healthcare professionals in PNG on how best to manage HIV/AIDS in local patients.

These actions, among many others, demonstrate the industry's commitment to help those most in need. Medicines Australia strongly believes that everyone deserves to have access to the most effective treatments, regardless of nationality, race or financial status. These are some of the many reasons why, for example, Medicines Australia strongly supports the implementation in Australia of measures consistent with the principles of the *Doha Declaration on the TRIPS Agreement and Public Health* (TRIPS Protocol), which would allow Australian companies to manufacture and export generic versions of patented medicines to countries facing sudden and major public health emergencies.

CONCLUSION

Retaining and growing global investment in medical research in Australia is a unique opportunity for Australia to derive significant economic benefit, significant societal health improvements and also knowledge transfer to Australian researchers. The ability of local companies, research institutes, universities and other relevant bodies to retain and grow this investment is almost completely dependent on Governments and stakeholders working together to design and implement policies which enhance the productivity, timeliness and quality of conducting medical research in Australia, while reducing the cost.

Australia's local strengths, the quality of our medical research and health system, have provided a strong competitive advantage in the past. This advantage is declining for a number of reasons, not least of which is the rapidly improving quality of medical research conducted in other countries.

For investment in clinical research specifically, Australian companies face accelerating competition from India, China and emerging markets in Eastern Europe, which, in addition to their growing commercial importance as growth markets for pharmaceuticals, are increasingly able to leverage massive patient populations, significant cost advantages, skilled labour and increasingly sophisticated health care systems to attract investment. In this context, increasing timeliness, productivity and lowering the cost of conducting this research in Australia is vital to leverage local strengths more effectively and more sustainably.

Australia can maintain a competitive advantage in all aspects of research and development. Medicines Australia believes that governments and stakeholders have to work together to ensure that Australia's research and development capabilities, including health care institutions and allied personnel, can be leveraged as effectively as possible to attract sustained investment in medical research.