MEDICINES Australia

Issues Brief
5 Innovation

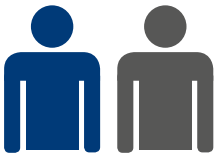
SUPPORTING AUSTRALIA'S EXTRAORDINARY RESEARCH TALENT

As a nation, we should be proud of our record in innovation. Australia is home to extraordinary research talent. The sort of talent that can create breakthroughs in medicine and lead to better health outcomes for all Australians.

Medicines Australia believes that constructive research collaboration is key to unlocking the full potential for innovative medicines in Australia.

OBJECTIVES BRIEF 5:
INNOVATION

Medicines Australia strongly encourages the Australian Government to:

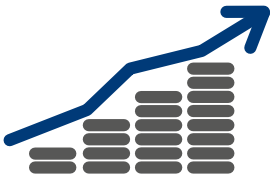


Review and enhance research funding schemes to encourage more collaboration between the universities and business.

Establish a Centre of Excellence to evaluate health and medical research (H&MR) proposals based on commercialisation criteria.

Continue to fund the $250 million Biomedical Translation Fund (BTF) to support investment in commercialising biomedical innovation.

Increase current levels of investment in H&MR.



Restore targeted measures for business research and development (R&D) through a long-term plan for the medicines industry.

Key fact:
The medicines industry invests **$1 billion** annually in Australian R&D.

OVERVIEW

Australia's extraordinary talent has developed some ground-breaking discoveries.

These discoveries are helping to fight previously untreatable diseases and are providing patients with better survival rates and improved quality of life.

Australia's research activities occur in publicly funded research organisations, private research organisations, universities and innovation orientated businesses.

Medicines Australia member companies are leaders in commercialisation of research and investment in innovation.

Australian researchers have a record of delivering when it comes to innovation. Overall research into clinical medicine sees Australia performing well above the world average.

Australia is one of the top three countries for life expectancy due in no small part to the amazing innovations in medicines, some discovered in Australian research laboratories.

The Organisation for Economic Cooperation and Development (OECD) notes that Governments play an important role in fostering investment in R&D and innovation by offering direct support or indirect support. According to the OECD's definition:

> Government direct R&D funding includes grants, loans and procurement. Government indirect R&D funding includes tax incentives such as R&D tax credits, R&D allowances, reductions in R&D workers' wage taxes and social security contributions and accelerated depreciation of R&D capital.
>
> Source: Measuring Innovation: A New Perspective, OECD 2010

CHALLENGE: ABOLITION OF STRATEGIC BUSINESS INVESTMENT IN THE MEDICINES INDUSTRY

No specific investment scheme exists to encourage R&D and production in the medicines industry since the PIIP ended in 2009.

For over thirty years, the Australian Government set aside additional funding to strategically support industries it regarded of significance for the nation. A number of grants programmes administered over 1988–2009 provided direct support to the medicines industry. These programmes were key parts of Australia's R&D architecture.

When the medicines industry was facing declining investment, the then Australian Government introduced the Factor F scheme which ran from 1988 to 1999. The scheme encouraged companies to make significant manufacturing and R&D investments in Australia through notional price increases for products supplied through the Pharmaceutical Benefits Scheme. Over the 10 years the scheme was in operation, the medicines industry conducted more R&D and manufactured more high-value therapeutic products for domestic and export markets.

In 1999, the Australian Government announced the Pharmaceuticals Industry Investment Program (PIIP) as a follow-up to Factor F. This 5-year programme with $300 million in available funding, operated from 1999 to 2004. In a 2003 review, 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."

The scheme was extended but eventually ended in 2009. No new models were implemented as an alternative.

Australia's Chief Scientist advises that business R&D could be further supplemented with more targeted incentives such as grants, loans and procurement-linked support schemes.[1] It's been recommended that the Australian Government rebalance support for business R&D through direct forms to better target R&D priorities.

1. Australian Chief Scientist, Submission to Inquiry into Australia's Future in Research and Innovation Joint Select Committee on Trade and Investment Growth.

SOLUTION: AUSTRALIA'S FUTURE R&D ARCHITECTURE – A CASE FOR TARGETED R&D INVESTMENT INCENTIVES?

In light of the clear commitment from the Australian Government to reform Australia's R&D architecture, restoring targeted measures of support could help to realise the objective of encouraging sustainable growth in key industries and help to create a modern, dynamic, 21st century economy.

The Australian Government has placed a significant emphasis on innovation policy over the last 18 months. Policies are being refocused to drive innovation in areas where there are growth prospects.

The Chief Scientist has been given oversight of a whole-of-government 10–15 year plan for innovation and science investment. A number of new measures are being implemented including 'industry growth centres' for Australia's most promising sectors:

- food and agribusiness;
- mining equipment, technology and services;
- oil, gas and energy resources;
- medical technologies and pharmaceuticals; and
- advanced manufacturing.

These growth centres are designed to encourage businesses to form commercial R&D partnerships with each other, and with the research sector.[2] It is pleasing to see that the medicines industry is regarded as one of the key industries with great potential.

The amount of medicinal and pharmaceutical exports has been declining since 2013, but there are some recent signs that this trend might be reversing. Read more on the levels and types of exports generated by the medicines industry in Medicines Australia's Issues Brief on Investment (No. 4).

There are currently only a handful of direct sources of funding available to support business R&D. It is timely to revisit the issue of additional investment in the medical technologies and pharmaceuticals industries, given they are once again regarded as strategic priorities.

The Victorian Government recently released a Medical Technologies and Pharmaceutical Sectors Strategy as part of a broader plan to grow future industries. Funding of $200 million has been made available to support the implementation of the strategic plan. The funding is reserved for industry sectors that have the potential to drive significant jobs growth and attract investment.

The Medical Technologies and Pharmaceuticals Growth Centre (MTPConnect) is developing a 10-year strategic plan to encourage the growth of these industries.[3] While it is acknowledged there are currently constraints on the federal budget, future funding could be attached to the long-term plan.

Possible models of targeted support for business R&D to consider include those outlined in a Deloitte (2008) evaluation before the PIIP scheme ended. A new scheme with the purpose of facilitating 'partnership' investments involving medicine companies and the public research sector was put forward.[4]

It was envisaged that partnership investments could potentially achieve higher levels of inducement and higher spill-over benefits through the provision of long-term infrastructure that would benefit multiple parties. Deloitte concluded that the net economic impact of introducing such a programme may potentially be higher than previous programmes.

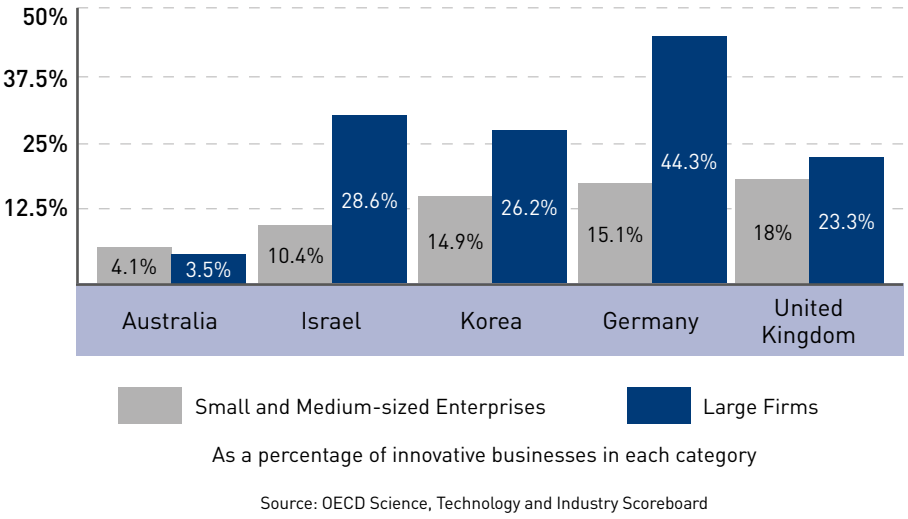
2. https://www.dpmc.gov.au/sites/default/files/publications/IICA_fact_sheet_industry_growth_centres.pdf;
3. MTPConnect, accessed 30 June 2016 at: http://www.mtpconnect.org.au;
4. Deloitte Insight Economics for the Department of Innovation, Industry, Science and Research, Evaluation of the PPPI program, final report, May 2008.

CHALLENGE: BUSINESS COLLABORATION WITH HIGHER EDUCATION AND PUBLIC INSTITUTIONS

In recent years, numerous inquiries and reviews have concluded that difficulties capitalising on research investments occur because of low levels of collaboration.

The Department of Industry and Innovation (2016) estimates that just 5% of R&D grant expenditure involve links between business and universities.[5]

GRAPH 1: BUSINESS COLLABORATION WITH HIGHER EDUCATION



As a percentage of innovative businesses in each category

Source: OECD Science, Technology and Industry Scoreboard

As Graph 1 above illustrates, in comparison with other countries in the OECD, Australia performs poorly on the level of collaboration between researchers in higher education and business.

In recent years, numerous inquiries and reviews have concluded that difficulties capitalising on research investments occur because of low levels of collaboration. This difficulty is particularly apparent with respect to small and medium sized businesses.

While only a relatively small proportion of research is undertaken directly by the Australian Government, it is responsible for administering funding. This includes competitive grants provided through the National Health and Medical Research Council (NHMRC) and Australian Research Council (ARC), to assist hospitals, higher education and Medical Research Institutes (MRIs) conduct a range of research activities.

The Australian Government's National Innovation and Science Agenda (NISA) signals a number of important adjustments. The NISA has been developed to assist in boosting the commercial returns of publicly-funded research.

New measures under the NISA include how higher education institutions can be funded, and performance managed, so as to encourage more collaboration between universities and business. The Australian Research Council (ARC) is currently consulting on possible metrics that measure the ways in which universities clearly engage with industry.

5. http://industry.gov.au/Innovation-and-Science-Australia/Documents/Speech-Sydney-11-February-2016.pdf

SOLUTION: MORE PUBLIC AND PRIVATE PARTNERSHIPS

Collaborative public-private partnerships demonstrate how it is possible to both reduce duplication in research and enhance the pace of discovery and commercialisation.

The tables below provide two private and public partnership case studies. These partnerships are between Medicines Australia member companies and higher education institutions.

CASE STUDY 1: PARTNERSHIP BETWEEN GSK AND MONASH (UNIVERSITY) INSTITUTE OF PHARMACEUTICAL SCIENCES (MIPS)

GSK and Monash (University) Institute of Pharmaceutical Sciences (MIPS): the joint initiative brought together Monash University's world-leading drug delivery and formulation development expertise and GSK's industry and manufacturing capabilities. The collaboration involved the translation of cutting-edge science into next-generation pharmaceutical products destined for the national and international market. The partnership involved the blow-fill seal technology utilised at GSK's Boronia advanced manufacturing facility in Melbourne.

CASE STUDY 2: PARTNERSHIP BETWEEN JANSSEN (J&J) AND UNIVERSITY OF QUEENSLAND

Janssen (J&J) and University of Queensland: The UQ signed an R&D and licence agreement with Janssen to identify, develop and commercialise small molecule modulators of a biological target identified by UQ as being important for the treatment of ankylosing spondylitis and potentially psoriasis and inflammatory bowel disease. Experts suggest that inflammatory bowel diseases are conditions that affect 2–3% of the world's population and for which there is great need for better treatments.

To encourage public and private partnerships, future ARC grant criteria should continue to focus on industry partnerships. Criteria should include new metrics to help ensure that new research is given every opportunity to be turned into a commercial success.

The medicines industry hopes that the Australian Government's new $7 million policy to encourage more clinical trials will also help to facilitate more public and private partnerships. Medicines Australia's Issues Brief on Clinical Trials (No. 6) provides further options on how specific commitments in this policy area could be implemented.

A review of the NHMRC grants programme also provides a further opportunity to examine how to increase the number of public-private partnerships.

Advice is to be provided to the Australian Government on whether the suite of funding schemes can be streamlined by the end of 2016. This is in response to concerns that in recent years, research costs and total application numbers have continued to rise. These challenges place a heavy burden on applicants and peer reviewers. Previous reviews such as the McKeon review found that NHMRC grant applications are overly complex and overly time consuming, with researchers spending up to a quarter of their time preparing applications.

Optimising the efficiency of local clinical trials will improve our competitiveness as a destination for international investment.

Another key recommendation was to drive more collaboration in the H&MR sector and encourage greater interaction with industry through clinical trials. To help achieve this, options put forward included dramatically reducing the number of ethics committees and streamlining governance review processes to make it simpler to start new clinical trials. Medicines Australia welcomed many of the McKeon review recommendations, including those to expedite the efficiency of conducting clinical trials and improve our competitiveness as a destination for global investment.[6]

6. https://medicinesaustralia.com.au/media-release/mckeon-review-on-the-money-with-health-and-medical-research

HIGHER EDUCATION INSTITUTIONS AND BUSINESS LEAD THE WAY IN RESEARCH

TABLE 1 – LOCATION OF H&MR EXPENDITURE IN AUSTRALIA

Australian Government	States & Territories	**Higher Education**	Not-For-Profit	**Business**	Total
198	479	**3,271**	824	**1,124**	5,896
3%	8%	**56%**	14%	**19%**	100%

Source: Research Australia, Australian H&MR Research Facts, 2016.

Table 1 above demonstrates that the majority of direct expenditure in H&MR occurs in higher education institutions with around 19% of Australian expenditure occurring in business.

The opposite is the case for indirect funding, with tax incentives being the main form of support for business innovation. Medicines Australia's Issues Brief on the Business Environment (No. 3) covers issues relating to fiscal measures which support investment in innovation.

7. Research Australia, http://researchaustralia.org/australian-research-facts

CHALLENGE: AUSTRALIA'S COMMERCIALISATION OF RESEARCH NEEDS TO IMPROVE

Despite our research institutions performing in the top 10 for quality, our capacity for innovation is ranked just 23rd out of 189 countries.

Source: Global Competitiveness Report 2013–2014

While Australia performs well on research excellence, evidence suggests we are not performing as well compared internationally when it comes to commercialising research outcomes. This suggests that there is scope for improvement.

Results from the Global Competitiveness Report for 2013–2014 reveal Australia's excellence in terms of the quality of its scientific research institutions (eighth out of 148 countries). Australia scores in 15th place for university-industry collaboration. On the other hand, investment in R&D by Australian companies scores a 30th place and our capacity for innovation is ranked 23rd.

The Australian Government's policy to develop Australia's research capabilities includes a long-term commitment to increasing levels of investment in H&MR.[8]

The Medical Research Future Fund (MRFF) is designed to provide a sustainable source of funding. With around $400 million committed over the first few years, it is expected to rise to $1 billion a year once fully established. The funding is in addition to the $850 million for medical research provided through the Medical Research Endowment Account.

In recognition of the need to improve the commercialisation of research, Medicines Australia supports continued investment in the BTF. The scheme includes $250 million from the Australian Government matched by funds from the private sector (making it $500 million) over two years to commercialise biomedical discoveries.

8. https://www.liberal.org.au/coalitions-policy-develop-australias-medical-research-capabilities

SOLUTION: ACCELERATING THE COMMERCIALISATION OF HEALTH AND MEDICAL RESEARCH

The creation of a centre of excellence for fast-tracking commercialisation of research for new medicines would pair researchers with commercial partners early in the research process.

The future growth of our economy will depend on greater commercialisation of research. The establishment of the MRFF provides Australia with the chance to become the world-leader in medical research. It will help to attract some of the world's best scientists, researchers and healthcare professionals to Australia.

Members of the Australian Medical Research Advisory Board set out the strategies and priorities to inform decisions by Government. In developing these priorities the Board is considering:

- the burden of disease on the Australian community;
- how to maximise the practical benefits from medical research to as many Australians as possible; and
- how to ensure that funding under the MRFF complements and enhances other financial assistance provided for medical research.

Medicines Australia supports the development of a coherent, national set of strategic research priorities for the MRFF that encourages research in the areas of the national health priorities.

Medicines Australia has proposed the creation of a "Centre of Excellence" to focus on translation and commercialisation of medical research for new medicines. It makes sense to strengthen the relationship between public agencies responsible for research, universities and research institutes with industry, through the establishment of a dedicated Centre of Excellence.

The proposed Centre of Excellence for commercialisation of medical research would link researchers with commercial partners early in the research phase, identifying the pathway through which the research, if successful, can be carried forward by a commercial partner.

This will then provide a clearer incentive for ongoing investment by other parties and the development of future partnerships (including with the innovative pharmaceutical industry). The interface with industry is important to link researchers with those who have more detailed information on how research can be brought to market.

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EXECUTIVE SUMMARY

A COMMON GOAL

A strong innovation sector that leads the world in commercialising breakthrough medicines.

KEY CHALLENGES

- The abolition of targeted investment in the medicines industry – at this moment, no specific investment scheme exists to encourage R&D and production value-add in the local medicines industry.
- A lack of business collaboration between higher education and public institutions – in comparison with other countries in the OECD, Australia performs poorly on the level of collaboration between researchers in higher education and business.
- Australia's commercialisation of research needs to improve – while quality is high, investment in R&D by Australian companies scored a 30th place and our capacity for innovation ranked 23rd in the Global Competitiveness Report for 2013–2014.

KEY SOLUTIONS

- Restore targeted measures of support for R&D to encourage long-term sustainable growth and partnerships between the medicine companies and the public research sector.
- Encourage business-university partnerships early in the R&D process to enhance the pace of discovery and commercialisation of innovative medicines.
- Support the development of a coherent, national set of strategic research priorities for the MRFF that encourages research in the areas of the national health priorities.
- Establish a "Centre of Excellence" to focus on translation and commercialisation of medical research for new medicines, linking researchers with commercial partners early in the research phase, to identify the pathway through which the research, if successful, can be carried forward by a commercial partner.