



Medicines
Australia

Federal Budget Submission 2019

Our choice for a healthier future



About Medicines Australia

Medicines Australia is the industry association for the innovative pharmaceutical sector. Our members invent, research, manufacture and supply innovative and breakthrough medicines and vaccines that help people to live longer, healthier lives. These medicines and vaccines keep Australians out of hospital, prevent disease and play a pivotal role in ensuring a productive and healthy community. Our membership consists of nearly 90 per cent of Multinational corporations of the medicines sector, all of whom are committed to advancing the health outcomes of all Australians.

Accordingly, Medicines Australia is driven to provide longer and healthier lives for Australians through the ability to choose from a range of quality, world leading innovative medicines.

We partner with key stakeholders, drive the creation and development of a predictable environment for the continued, sustainable growth of the innovative and research-based prescription medicines industry.

It follows that Medicines Australia leads and maintains industry consensus and unity to contribute to essential medicines policy development for the benefit of all Australians.



Medicines Australia aims to:

1. Be an industry role model to build unity and strength.
2. Achieve a predictable and stable environment for the registration and reimbursement of medicines in Australia.
3. Work with the Australian Government to actively create a favourable environment for investment by the medicines and vaccines industry.
4. Strengthen the reputation of the industry.



Who we work with:

We aim to achieve our objectives by forming effective alliances, including engaging with the Parliament, Government and government departments, other peak bodies in the medicines industry, health consumer groups, health professionals and academic institutes to develop health and industry policy, conduct clinical trials, fund academic work and formally contribute on scientific projects.

Introduction

Investing in the supply of innovative and breakthrough medicines to provide universal, subsidised access for the Australian community is a fundamental undertaking of the Australian Government. Since its inception in the 1950s, the Pharmaceutical Benefits Scheme (PBS) has been one of the most critical components of the Australian healthcare system. Its intent is to subsidise the cost of medicines to ensure that the latest innovations in treatments can be made affordable and accessible to all Australians. For this reason, the PBS was designed as an uncapped programme to ensure the swift availability of new medicines and vaccines in Australia.

Investing in new, innovative medicines has been shown to provide incredible value and benefits to the community. According to the report *'Our Health, Our Wealth: The Impact of Ill Health on Retirement Savings in Australia'* (available at www.medicinesaustralia.com.au), produced in partnership with the McKell Institute, early retirement due to ill health imposes a significant economic cost, almost 4.5 times government expenditure on the Pharmaceutical Benefits Scheme in 2016–2017. Medicines Australia argues that it is very important to consider ways to address this and take action while illness may be more manageable, to retain a person's ability to function effectively and remain in the workforce.

Lichtenberg (2017) found that \$7 billion was saved in hospital expenditure in 2011 alone due to the ongoing investment in, and listing of, innovative medicines on the PBS. The same study found that the listing of innovative medicines on the PBS was the major factor in the 33% decline in premature deaths in Australia between 1997 and 2012¹. Other studies have also shown the role that innovation in medicines has played in boosting productivity in Australia by helping people to either stay at work or return to work sooner².

Despite the demonstrable growth in other areas of health such as the MBS, PBS growth has been historically flat or in decline (in real terms) since 2011. We note that while the latest PBS figures show an approximate growth of 7%, the long-term trend is in decline in real terms. We reiterate the clear value and benefits of keeping a strong PBS and encourage continued investment of this kind.

The Strategic Agreement signed between Medicines Australia and the Commonwealth in April 2017 has given some stability and focus for the next five years, but big challenges lie ahead. The challenge for government, the community, and industry is to ensure that the PBS can fully fund the needs and demands of patients, not just for today's medicines and vaccines, but tomorrow's advancements in innovative therapies. Over the past decade, Australia's innovative medicines industry has worked with successive governments on fundamental PBS reforms delivering more than \$20 billion in ongoing savings. The Strategic Agreement is designed to lock in further savings in every year of the budget forward estimates through to 2022, totalling an approximate \$1.8 billion. Naturally, there will be fluctuations in the savings over the forward estimates depending upon market conditions, including the entries and exits of different products – this makes the savings somewhat irregular. Accordingly, governments have undertaken to provide a series of process reforms and to provide a stable, predictable business environment to support the industry's ongoing investment in 23,000 local jobs, medical research partnerships and clinical trials delivering huge and incalculable benefits to the Australian community.

1 Lichtenberg, Frank R. (2017), 'The Impact of Pharmaceutical Innovation on Premature Mortality, Hospital Separations, and Cancer Survival in Australia', *Economic Record*, 93, 302, p.353-378, <http://onlinelibrary.wiley.com/doi/10.1111/1475-4932.12332/full>

2 Schofield, D. et al. 'Measuring Labour Productivity and the Benefits of Interventions for Osteoarthritis', project report for Medicines Australia, <http://corporate.medaus.com.au/wp-content/uploads/sites/52/2010/01/20160905-rpt-FINAL-Schofield-OAproductivity-final-report.pdf>

The Medicines Australia 2019-2020 Budget Submission is the continuation of a conversation about the viability and sustainability of the PBS and its ability to properly fund new medicines. According to a recent analysis by PWC³, our members contributed \$9 billion to the Australian economy in 2016-2017, which supported the employment of almost 23,000 Australians (direct and indirect). The medicines industry continues to be one of the largest exporters of elaborately transformed manufactured goods with some of our members expanding their advanced manufacturing facilities and capabilities in Australia. Our members continue to be significant investors in Australian R&D, including one thousand clinical trials initiated in 2016-2017 that helped 33,000 Australians get early access to emerging therapies.

To support this ongoing contribution to the Australian community and economy, the Government needs to maintain not just a well-funded PBS, but also continue to support industry-focused policy settings, such as the R&D tax incentive. These are important enablers to encourage investment by our members into Australia's medical technology and pharmaceutical (MTP) sector.



A snapshot of the innovative medicines industry

- Contributed nearly **\$9 billion** to the Australian economy in 2016 through direct and indirect contributions.
- Employs nearly **23,000** people across 78 offices and facilities, who live in over 850 different postcodes including in rural and regional Australia.
- Support about **20,000** additional business including over 2,000 small businesses.
- Conducted nearly **1,000** clinical trials in 2016, enabling over 33,000 Australians to access potentially life changing new medicines.
- Invested **\$270 million** in clinical trials in 2016.
- Invested over **\$1 billion** in collaborative and strategic partnerships.
- Shared our ideas, resources, IP and technologies with universities, patient groups, health care providers, researchers and start-ups and bio-tech companies.

SOURCE PricewaterhouseCoopers Consulting (Australia) Pty Limited (PWC Consulting): The economic contribution of the innovative pharmaceutical industry to Australia. December 2017.

3 Figures from a yet to be published PWC survey of Medicines Australia member companies, "The economic contribution of the innovative pharmaceutical industry to Australia"

Executive Summary

The priorities for the 2018-2019 Budget for the innovative medicines industry are focused on the following key areas:

1. Accessibility and value: putting Australians' health first
2. Innovation and investment: growing Australia's medicines industry
3. Improved policy coordination throughout the whole of medicines sector
4. Digital health
5. Employment and skills.

1. Accessibility and value: putting Australians' health first

IMPROVEMENTS FOR PATIENT ACCESS TO MEDICINES

Australians should have access to the latest medicines they need when they need them. This is dependent on the sustainability and viability of the PBS. A five-year Strategic Agreement between Medicines Australia and the Commonwealth will support ongoing access to the latest innovative medicines for patients. This Agreement acknowledges the need for growth in the PBS to accommodate a growing and ageing population, the increasing burden of chronic disease and the advent of extraordinary advances in technology to deliver innovative medicines and therapeutics. The Agreement contains specific deliverables and targets that relate to the importance of the innovative medicines sector and continuous improvement of assessment processes. Alignment of expedited Therapeutic Goods Administration (TGA) and Pharmaceutical Benefits Advisory Committee (PBAC) processes has a significant role to play in the delivery of rapid access to the latest advances in medicines and vaccines.

Action 1

The Australian Government, through the Department of Health, works with Medicines Australia to ensure full implementation of the Strategic Agreement. This includes the pricing measures (Clause 5); the reserving of all savings for future listings (Clause 6); modernisation of e-prescribing and data capacity (Clause 7); and listing process improvements to accelerate PBS availability of world leading medicines for patients (Clause 10).

Within this, we recommend that the Australian Government provide greater resourcing to the Department of Health to ensure the timely delivery of the agreed reforms and process improvements. Medicines Australia seeks this resourcing commitment in the upcoming budget, in acknowledgement that the industry is delivering on its funding commitments through legislative changes and consultation on revised cost recovery arrangements.

Action 2

The Australian Government, through the Department of Health, to commit to provide regular reports on the progress made against the deliverables specified in the Strategic Agreement. These include:

- development of revised pathways, principles approved by the Minister;
- doubling access to early advice on submissions for new medicines;
- reducing the time taken for medicines to be available through listing on the PBS by at least two months;
- 50% reduction in resubmissions;
- streamlining of costs for complex submissions;
- on-line submissions process for applications; and
- alignment of PBAC process in parallel to changes made to TGA processes.

Accordingly, Medicines Australia acknowledges the value of the Joint Oversight Committee (JOC) and recommends the implementation of Key Performance Indicators to monitor the delivery of Strategic Agreement outcomes.

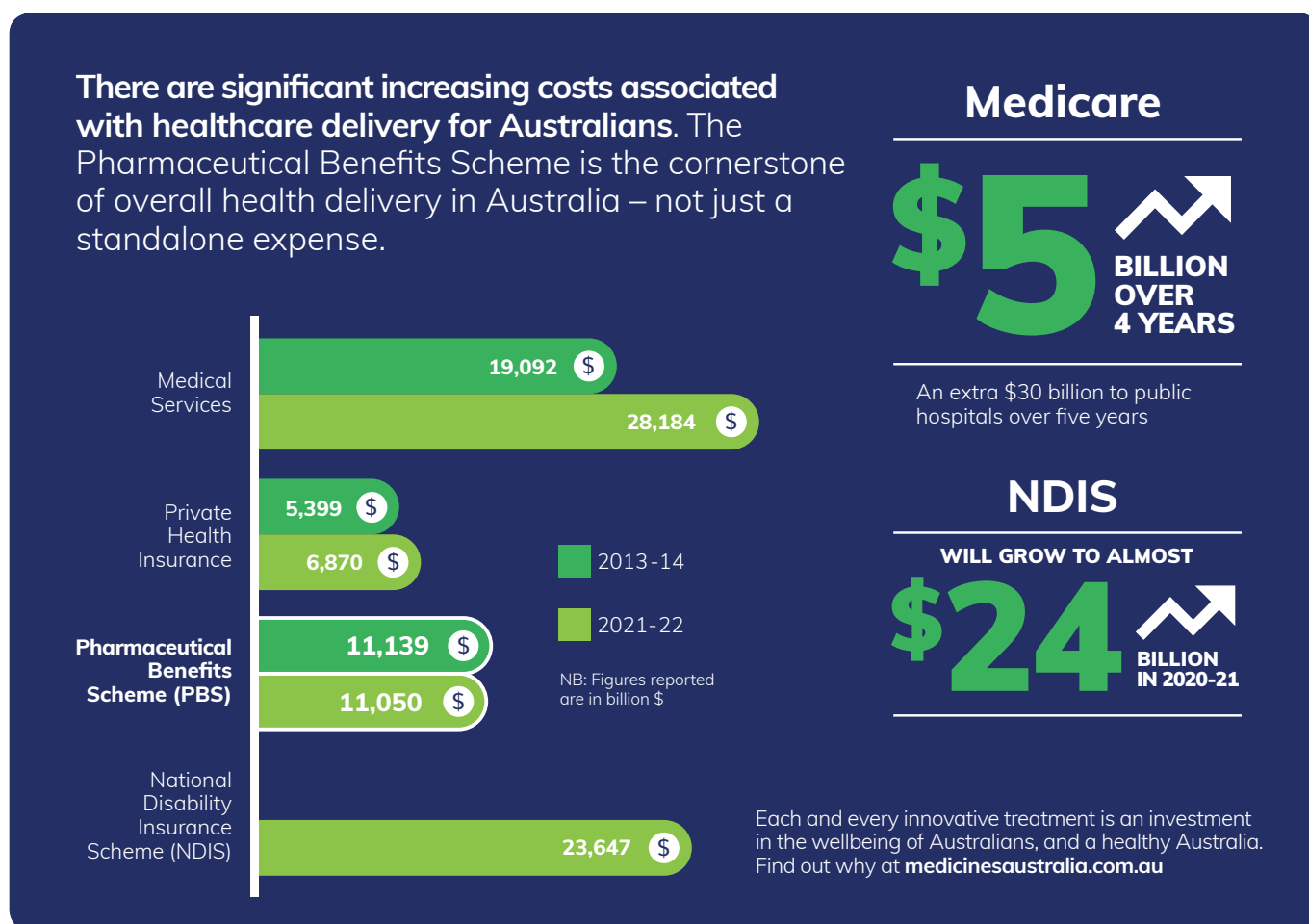
EXPLAIN THE TRUE COST OF MEDICINES TO THE TAXPAYER WITH REPORTING ON PBS EXPENDITURE

Action 3

Medicines Australia would like to see the current levels of reporting on the supply chain continue to be strengthened. We recommend that this include a breakdown of reporting into medicines and distribution channels. We believe that this will help to demonstrate the substantial value for money that the innovative medicines industry provides to the Australian taxpayer.

Action 4

Timely access is also critical to this process. We recommend that positive PBAC recommendations be approved by Cabinet within a six month time frame.



SOURCE: Federal Government. Budget Papers. https://www.budget.gov.au/2016-17/content/bp1/html/bp1_bs5-01.htm. Accessed September 2018

2. Innovation and investment: growing Australia's medicines industry

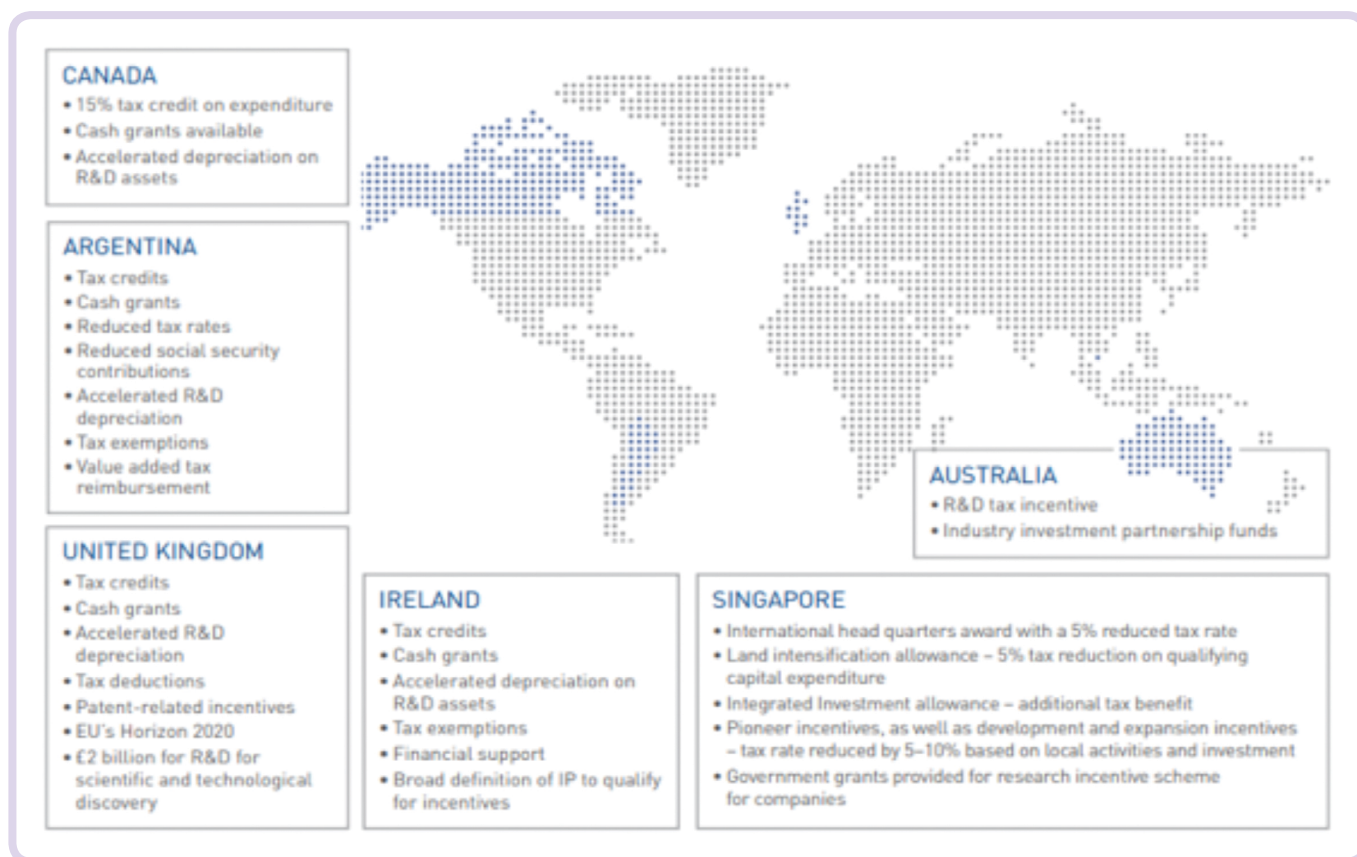
Pharmaceuticals and vaccines are a significant advanced manufacturing export market for Australia. Currently, Australia exports about \$3 billion of vaccines and medicines. There are exciting opportunities for Australia to grow its share of international medicines and vaccines trade, with global demand for medicines expected to double in a decade (DFAT, 2016). Making the most of this opportunity will help to drive economic growth, deliver more high-skills jobs, and provide Australians with improved access to medicines. Our industry sees opportunity for growth in advanced manufacturing. Much of this growth will come from partnerships and investment in Australia's research and biotechnology industry. This industry has the skills and capacity to construct niche, innovative manufacturing plants which will deliver jobs for STEM graduates.

The National Innovation and Science Agenda (NISA), a whole-of-government 10-15 year plan, has been put in place to encourage innovation. It includes a dedicated industry growth centre in MTPConnect and the Medical Research Future Fund (MRFF). The innovative medicines industry is a natural partner to the NISA, as the sector is primarily driven by research. This research relies on highly-talented researchers, including world-class clinicians. Many of these clinicians work on clinical trials or research in collaboration with the innovative medicines industry.

Our relationship with MTPConnect has reinforced to Medicines Australia the value of having a targeted industry growth centre.

Australia's extraordinary talent has enabled the development of ground-breaking discoveries. According to OECD Health Statistics 2015, we are one of the top 10 countries for life expectancy due in no small part to the remarkable innovations in medicines, some discovered in Australian research laboratories. Medicines Australia member companies are leaders in commercialisation of research and investment in innovation, and with the establishment of the MRFF, Australia is in the prime position to become the world-leader in medical research.

Our aim is to work with the Government to build Australia's commercialisation capability at all stages of medicines and vaccines development. As the figure below demonstrates, our major international competitors have a range of incentives in place in order to attract investment to their country, including tax credits, grants, loans and exemptions. MTPConnect developed a 10 year strategic competitiveness plan to encourage the growth of these industries. In conjunction with this, the Government has also begun dispersing funds from the BTF and the MRFF. Both these funds will have a positive impact on the sector and should be continued. As part of these efforts, we look forward to realising a new vision of medicines and vaccines R&D in Australia, to attract new investments to this country.



SOURCE Adapted from EY, 2013-2014 Worldwide R&D incentives reference guide, and Singapore Government, Incentives for businesses.

Action 5

While it is acknowledged there are currently constraints on the Federal Budget, consideration could be given to introducing loans instead of grants as part of this long-term plan. Australia's Chief Scientist advises that business R&D could be further supplemented with more targeted benefits such as grants, loans and procurement-linked support schemes. A number of grants programmes in operation from 1988–2008 formed the backbone of Australia's R&D architecture. Instead of grants, a loans system could help provide an incentive for companies to invest in an industry that has been identified by the Australian Government as being a growth area for the economy during the transition from the resources boom.

INTELLECTUAL PROPERTY

Aligning our intellectual property (IP) protection regime with those of our key trading partners will boost Australia's competitiveness and strengthen Australia's reputation. We share the Australian Government's aspiration to build Australia's commercialisation capability. Our objective is to engage with investors in this country to take products from development to launch for the benefit of patients. The more Australia is aligned with other countries, the more we will compete effectively in the global race for investments in research, biotechnology and commercialisation of innovative medicines. There is an opportunity in the current IP environment in Australia to strengthen our IP system to better align with other jurisdictions. Our current system of five years' data exclusivity and an average 12 years of effective patent life are less attractive than comparable innovation and investment driven systems in other OECD countries with whom we compete.

Action 6

Aligning our IP protection regime with those of our key trading partners will boost Australia's competitiveness and strengthen Australia's reputation. This includes increasing data exclusivity to 10 years.

Action 7

Ensure innovative medicines achieve 15 years' effective patent life.

Action 8

Establish a time-limited working group through MTPConnect to model the benefits to the economy and any challenges of implementing ten years' data exclusivity in Australia. A strong and reliable Intellectual Property system drives innovation and accords with the broader policy objectives to grow the biopharmaceutical sector and enable greater biopharmaceutical innovation to contribute to economic prosperity; for this reason the Government should commit to maintaining, and indeed strengthening Australia's IP systems.

CLINICAL TRIALS

Australia's innovative medicines industry conducted nearly 1,000 clinical trials in 2016, giving 33,000 Australians free, early access to potentially life-changing new medicines. A thriving clinical trials sector can bring value to the Australian economy and advance public health outcomes.

Clinical trials are critically important to Australia because results of clinical trials can lead to the development of new medicines that can assist Australians treat and manage their condition. They also create employment opportunities in our research organisations, universities and hospitals. The innovative medicines industry is an important partner in investment and collaboration with scientists, doctors and research centres involved in clinical trials. Without this investment and collaboration, many clinical trials would not be viable. Efficient quality assurance of clinical trials is critical to improving health outcomes and the overall productivity of the economy. But the differences in ethics approvals and research governance systems, even intra-state, are costing Australia's global competitiveness and hampering its potential to attract clinical trials.

We encourage the Government to continue its work with COAG to develop a standard template and associated guidelines, including reasonable timeframes, to streamline ethics and governance approval processes for clinical trials across Australia.

Action 9

Market the value of clinical trials in Australia to global markets, building on Australia's reputation as a world class destination for investment. This may take the form of a shared model with State and Territory governments. Accordingly, the Government should continue to ensure that Australian approval times for clinical trials are world leading.

Action 10

Better coordination and data-sharing arrangements for clinical trials to accelerate the development of new technologies and treatments.

UPDATE THE NATIONAL MEDICINES POLICY

In this very exciting time of rapid advancements in modern medicine, a range of new technologies will become available to patients over the next decade and beyond. While the National Medicines Policy (NMP) has served Australia well for a very long time, it needs modernisation to ensure it remains fit for purpose into the 21st century.

Medicines Australia was pleased to initiate opening the dialogue in this policy space, having facilitated an early stakeholder roundtable on this topic.

Action 11

The Australian Government, through the Department of Health should work with consumers, targeted stakeholders and Medicines Australia and on the development of a National Medicines Policy update for the inclusion of emerging therapeutics. This will ensure the NMP remains fit for purpose and keeps pace with emerging therapeutic technologies and evolving health, medicines and therapeutics delivery systems. It would also guide future reforms to evaluation processes for therapeutics through the PBAC and PBS to accommodate emerging therapeutic technologies and ensure that all Australians who may benefit from a particular innovative treatment get access to it.

3. Improved policy coordination: whole of medicines sector

Medicines Australia advocates for the establishment of a high-level government-industry forum as a priority. Coordination, consistency and collaboration between the Department of Health and the Department of Industry, Innovation and Science, and with the Central Agencies, assists with the development of sound policies that lead to social, health and economic benefits for Australia through a vibrant medicines and vaccines sector.

Action 12

Ministers of Health, Industry, and where relevant, central agencies, to lead a government industry forum. This forum would develop policies that lead to greater social, health and economic benefits for Australia from investment in the PBS and the medicines and vaccines sector.

4. Digital health

Digital health can drive efficiencies across the health care system as a whole and improve patient outcomes, adherence and monitoring of medicines as they are used. Significant savings will accrue which can be reinvested in better healthcare interventions, such as innovative medicines on the PBS.

Medicines Australia sees the digital landscape as a substantial opportunity to harness greater efficiencies and better outcomes across the health system. We also encourage consideration of a robust digital health platform that can harness, engage and aggregate the vast amount of data available.

Data analytics in healthcare is evolving into a promising field for providing greater insights from sizeable data sets. Better use of health data can improve health outcomes while reducing the burden on the health system. Its potential is great; however there remain many challenges to overcome. Australia was regarded as a world leader in the 1990's with respect to Health Technology Assessment (HTA). It gained this reputation when it pioneered the use of economic evaluations as part of the approval process for medicines and vaccines. In more recent times, a number of reviews have been more critical of Australia's HTA processes. A revised framework that maximises health data opportunities could be coordinated by the Prime Minister and Cabinet's Digital Transformation Office in consultation with relevant portfolio agencies, funded from existing agency resources.

Action 13

Health Ministers continue to drive the necessary digital reform agenda by bringing forward the timeline for development of the *National Digital Medicines Management Blueprint*. This blueprint should ensure the inclusion of notification of dispensing actions back to prescribers to better track patients' health outcomes, treatment adherence and post market safety and efficacy monitoring of medicines (including identification of the use of biosimilar medicines).

Action 14

The Australian Government through the Australian Digital Health Agency (ADHA) should ensure the completion of the blueprint by 2018-2019.

5. Employment and skills

The strength of the medicines industry depends on the extraordinary talent of our people, their skills and knowledge.

A growing body of research predicts that the areas of future job growth will require people with higher levels of skills and education, particularly in STEM disciplines. Attracting and retaining talented researchers can be challenging due to factors such as employment uncertainty arising from short-term funding or more appealing career opportunities overseas. According to MTPConnect, funding from the BTF and the MRFF has the potential to make significant changes to the economy including:

- An additional \$3.2 billion in nominal Gross Value Added (GVA) compared to 2015, with GVA generated from 2015 to 2025 compared to the baseline estimated at \$18 billion; and
- An additional 28,000 new jobs to the sector in 2025 relative to 2015. Of these, 14,000 jobs are in universities and medical research institutes which reflects the substantial increase in research funding being delivered by the MRFF.

The Australian Government and State and Territories, through the COAG process, can improve long-term workforce planning and create incentives for companies to upskill their employees in knowledge intensive industries.

As an industry that employs STEM graduates, many with PhD level qualifications, there is a need to ensure that future graduates remain within the sector. For example, reduction of payroll taxes for STEM graduates would provide a tangible incentive for companies, and form part of the competitive localisation package offered by States and Territories for businesses to invest in their state.

Action 15

As a leading employer of tertiary educated Australians, we seek to work collaboratively with the Commonwealth Government to ensure that all measures that create employment opportunities are strengthened. This includes migration policies that allow our workforce to grow, knowledge sharing, education and training collaborations, and an appropriate R&D tax incentive.



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