

**MEDICINES**  
*Australia*

**FEDERAL BUDGET SUBMISSION**  
**2017/18**

# ABOUT MEDICINES AUSTRALIA

## WHO WE REPRESENT

Medicines Australia represents the discovery-driven pharmaceutical industry in Australia. Our member companies invent, research, manufacture and supply innovative medicines and vaccines to the Australian community. Those medicines keep Australians out of hospital, prevent disease and play a pivotal role in ensuring a productive and healthy community. Our membership consists of more than 50 companies, from established organisations to new startups, all of whom are committed to advancing the health outcomes of all Australians.

## OUR VISION

A longer and healthier life for Australians through availability and choice of world leading innovative medicines.

## OUR MISSION

In partnership 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 so Australians continue to lead longer and healthier lives.

## LEADERSHIP

Lead and maintain industry consensus and unity to contribute to medicines policy development for the benefit of all Australians.

## OUR STRATEGIC PRIORITIES

1. To be an industry role model and build unity and strength.
2. To achieve a predictable and positive environment for the registration and reimbursement of medicines in Australia.
3. To work with the Australian Government to actively create a favourable environment for investment by the pharmaceutical industry.
4. To strengthen the reputation of the industry.

## WHO WE WORK WITH

We aim to achieve our strategic priorities by forming effective alliances, including engaging with the Parliament, Government and government departments, other peak bodies in the medicines industry, consumer groups, health professionals and academic institutes to develop health and industry policy.

**MEDICINES**  
*Australia*

# CHIEF EXECUTIVE'S INTRODUCTION

Australia's medicines industry discovers and develops new treatments and vaccines. As an industry, we exist to innovate.

Advances in medicines have greatly improved lives over the last century and will continue to do so in the future.

Cutting-edge treatments have been able to deliver better health outcomes for patients with chronic, debilitating or even life-threatening diseases.

Smallpox, a disease that once killed up to 35% of its victims or left others blind has been eradicated. Polio has been reduced or eliminated in many countries through vaccination. New medicines for Hepatitis C are expected to increase the cure rate to 90%.

The medicines industry provides patients, as well as their families and the economy, with incredible value. Such innovations keep people out of hospitals; treat and prevent disease; and provide valuable export income for Australia.

In parallel with the health benefits, our industry supports around 15,000 high-value jobs; including in Science, Technology, Engineering and Mathematics (STEM) related fields. Developing new medicines is a resource-intensive, complex and time-consuming process. It involves collaboration with university-based and other researchers, contract research organisations, government regulators, hospitals, clinicians and patients. Each year around 700 clinical trials are commenced.

There is a clear mandate to nurture Australia's extraordinary research talent. As an industry that is intrinsically intertwined in the innovation process, we strongly support the National Innovation and Science Agenda (NISA). It is acknowledged that a number of Australian Government initiatives will help position our nation for long-term and enduring success:

- Establishment of the Medical Technologies and Pharmaceuticals Growth Centre (MTPConnect), to position Australia as a hub for medical technology and pharmaceutical companies.
- Setting up the Medical Research Future Fund (MRFF) and Biomedical Translation Fund (BTF) to support health and medical research and innovation, and the health and wellbeing of Australians.
- Review of the Research and Development Tax Incentive Programme, to improve the overall effectiveness and integrity of the scheme.
- Implementation of recommendations from the Medicines and Medical Devices Regulation Review (MMDR) to enable work sharing with, and use of assessment reports from comparable overseas regulators, and to establish expedited and priority approvals pathways for the benefit of Australian healthcare consumers.
- Harmonising the regulatory and research governance environment for clinical trials, by working with the States and Territories.

In our sector as in others, new ideas lead to new discoveries that provide Australia with the edge to compete internationally. These discoveries must be both rewarded and protected.

To compete with other advanced economies, we must have the right legislative and policy frameworks to attract both domestic and international investment. We also need to facilitate patient access for the treatments we produce.

Australia's healthcare system has gone through a period of rapid change. The Australian Government is being confronted by significant budgetary pressures that must be addressed over the long term.

An overview of some key challenges facing the industry are detailed in *Medicines Australia's Issues Briefing for the 45th Parliament*. These issues briefs explore some potential policy solutions over the short, medium and long term. We argue strongly that the sustainability and future of our healthcare system depends on many complex factors. Factors that fall outside of the scope of what can be covered in our pre-budget submission.

Medicines Australia has focused on short-term recommendations for this submission. These proposals (actions which are fully costed over the forward estimates) could be addressed in the 2017-18 Federal Budget or as budget circumstances permit. Given the recommended actions relate to a number of portfolio areas these have been set out in eight sections:

 <b>1. Value</b>	 <b>5. Innovation</b>
 <b>2. Access</b>	 <b>6. Clinical Trials</b>
 <b>3. Business Environment</b>	 <b>7. Intellectual property</b>
 <b>4. Investment</b>	 <b>8. Employment and Skills</b>

Better measurement, reporting and evaluation of health expenditure, the adoption of digital health solutions, the timely provision of life-saving medicines and vaccines and reduced regulatory delays are all solutions that can help our health system operate as efficiently as possible.

For Australia's medicines industry to thrive – as one that will drive economic success by encouraging innovation – responding to patients' needs and ensuring the sustainability of our health system is crucial.

The recommended actions proposed in this submission, while modest, would drive investment and innovation and assist policy-makers to gain a deeper understanding of how we might improve health outcomes over the longer term.



Yours sincerely



Milton Catelin,  
Chief Executive  
Medicines Australia

# EXECUTIVE SUMMARY

The priorities for the 2017-2018 Budget for the innovative medicines industry are:

## VALUE

The value of innovative medicines to Australia's health system is unquestionable. Investing in medicines helps to drive long-term economic growth. They make an important contribution to increased workforce participation and productivity.

### ACTION 1

#### Develop better productivity measures

The Australian Government's research and data collection programme should incorporate more sophisticated productivity measures as part of its data management improvements to better inform the Health Technology Assessment framework. Improving measurements of productivity is a challenge, but it's an important step toward a better health care system.

Inclusion of better productivity measures as part of the Government's long-term research and data programme will better inform policy development.

**Cost neutral**

### ACTION 2

#### Integrating big health data into long-term reporting frameworks

The integration of big health data into long-term reporting frameworks will significantly enhance the way in which the impact of health expenditure can be evaluated. The recent advancements in digital health and public access to de-linked Pharmaceutical Benefits Scheme (PBS) and Medicare Benefits Scheme (MBS) data provide great opportunities.

The provision of an open source government data programme, co-ordinated through Prime Minister and Cabinet's (PM&C) Digital Transformation Office would help government agencies and researchers make the most of big data opportunities and improve reporting on health expenditure outcomes.

**Funded from existing agency resources**

**(PM&C)**

## ACCESS

Reporting on the PBS expenditure against outcomes for different areas of the supply chain would make information about changes over time more transparent. The best outcomes in public policy emerge when the budget process is open, accountable, and transparent.

### ACTION 3

#### Update the presentation of PBS budget expenditure to account for the rebate(s) repaid by manufacturers

**Cost neutral**

### ACTION 4

#### Report PBS expenditure against outcomes for different areas of the supply chain

The operation and administration of the PBS is highly complex, involving manufacturers, Departments, prescribers, pharmacists, wholesalers and patients. While PBS expenditure is reported in annual reports and in budget documents, the presentation of information could be more transparent. The information on forward estimates of spending is very tightly restricted, limited to a few broad PBS expense categories. In recent years, while the operation and administration of the PBS has evolved, the budget reporting framework has not been updated to report on these outcomes.

**(Department of Finance/  
Department of Health)**



## BUSINESS ENVIRONMENT

Predictability in Australian Government policies creates a stable business environment, allowing our research based, innovative medicines sector to effectively plan for the future and generate high-value jobs.

### ACTION 5

#### Funding stability – innovative medicines industry

Reform of the PBS has been a partnership between Government and industry for over a decade. This partnership has delivered a significant, ongoing reduction in forecast PBS expenditure. However, reform has not been without its challenges, including job losses and changes to the investment behaviour of pharmaceutical companies in Australia. To ensure Australia maintains world-class access to innovative medicines, the Government should commit to a period of policy stability so that current PBS projections remain accurate. This will help industry to plan with confidence, continue to invest in their Australian operations (including Research and Development (R&D)) and bring the latest medicines to patients.

**PBS expenditure remains consistent with projections in current forward estimates**

### ACTION 6

#### Therapeutic Goods Administration upgrade of technology systems to support regulatory reforms

The medicines industry welcomes the Medicines and Medical Devices Review (MMDR) regulatory reforms, but emphasises the need for the Therapeutic Goods Administration (TGA) to implement them smoothly and efficiently.

It will be important to ensure that the TGA technology systems can support the revised regulatory processes needed to accelerate medicines access.

(Department of Finance/ Health)

(TGA)



## INVESTMENT

Restore targeted forms of support as part of a longer-term plan to encourage growth in the medical technologies and pharmaceutical industries.

### ACTION 7

#### Zero interest loans

Department of Industry, Innovation and Science to offer interest free loans for investment in advanced manufacturing facilities.

**\$75 million over five years**

### ACTION 8

#### Continue to support MTPConnect and its Project Fund Program

**MTPConnect funding – already budgeted over forward estimates**

(Department of Industry, Innovation & Science)



## INNOVATION

Constructive research collaboration is key to unlocking the full potential for innovative medicines in Australia.

### ACTION 9

#### Establish a Centre of Excellence

The Centre of Excellence, potentially in partnership with MTPConnect, will focus on translation and commercialisation of medical research for new medicines, linking researchers with commercial partners in the early phase.

**\$2 million over two years**



## CLINICAL TRIALS

A thriving clinical trials sector can bring value to the Australian economy and advance public health outcomes.

<b>ACTION 10</b>	<b>Market the value of clinical trials in Australia to global markets, building on Australia's reputation as a great destination for investment.</b>	<b>Shared model with State and Territory governments</b>
<b>ACTION 11</b>	<b>Create a national central point to harmonise clinical trials regulation.</b>	
<b>ACTION 12</b>	<b>Better coordination and data-sharing arrangements for clinical trials to accelerate the development of new technologies and treatments.</b>	



## 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.

<b>ACTION 13</b>	<b>Acknowledge the agreement contained in the recent Trans Pacific Partnership to increase data exclusivity to eight years.</b>	<b>Cost neutral</b>  <b>(Department of Industry/ MTPConnect/ Department of Health)</b>
<b>ACTION 14</b>	<b>Ensure innovative medicines achieve 15 years' effective patent life.</b>	
<b>ACTION 15</b>	<b>Establish a time-limited working group through MTPConnect to model the benefits to the economy and any challenges of implementing eight years' data exclusivity in Australia.</b>  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.	



## EMPLOYMENT and SKILLS

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

<b>ACTION 16</b>	<b>For STEM graduates, work with State and Territory governments to reduce payroll tax.</b>  Payroll tax is a burden for companies. The Australian Government as part of the tax reform measures should further commit to working with the States and Territories to reduce the rate of payroll tax for STEM graduates who are working in identified innovative industries such as pharmaceuticals.	<b>Exemption from payroll tax for the medicines industry for a maximum of 50 identified STEM and PhD graduate positions per company.</b>  <b>(Treasury and Council of Australian Governments (COAG))</b>
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# \$ VALUE

Investing in medicines helps to drive long-term economic growth. They make an important contribution to increased workforce participation and productivity.

The innovative medicines industry in Australia contributes to a healthy, productive and diverse economy where innovation, investment and jobs are created. The healthcare system should move toward a future-proofed state to meet the rising challenges that our evolving technological environment will no doubt bring.

Our industry is thinking about what health care delivery systems will look like in the future and how we can best enhance the lives and experiences of those that rely on our products – this vision is built upon the foundation of big data and analytics.

The creation of the new Public Data Branch within the Department of Prime Minister and Cabinet (PM&C) signals a renewed focus to smarter data policy, which is welcome.

**Big data analytics in healthcare is evolving into a promising field for providing greater insights from sizeable data sets. Better use of big health data can improve outcomes while reducing costs. 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).

## CASE STUDY 1 – UNIVERSITY OF SYDNEY PRODUCTIVITY PROJECT

Recent research produced for Medicines Australia shows that there is a link between investing in pharmaceutical interventions and increased economic outcomes.<sup>1</sup> In a small population case study for osteoarthritis, pharmaceutical intervention is estimated to lead to an additional 1,100 jobs in the labour force, an increase in tax revenue of \$11 million per year, and a reduction in welfare payments of nearly \$16 million. The net estimated increase in GDP as a result of this intervention was \$163 million.

As a case study of one condition utilising moderate treatment effects, this study shows that there are considerable unrecognised economic benefits from investing in life-saving innovative medicines that are not adequately captured or valued by the Health Technology Assessment system.

<sup>1</sup>Further information available on request.

It gained this reputation when it pioneered the use of economic evaluations as part of the approval process for pharmaceuticals. In more recent times, a number of reviews have been more critical of Australia's HTA processes.

A revised framework that maximises big health data opportunities could be co-ordinated by the PM&C's Digital Transformation Office in consultation with relevant portfolio agencies, funded from existing agency resources.

## MAXIMISE THE OPPORTUNITIES THAT BIG HEALTH DATA PRESENTS BY:

### ✓ ACTION 1

Including better productivity measures as part of the Government's long-term research and data programme which will better inform policy development.

### ✓ ACTION 2

Building on the provision of open-source Government data through the PM&C's Digital Transformation Office as part of the *Innovation Agenda* to allow further examination of healthcare provision, funding and coverage.

# ACCESS

Universal access to medicines is a foundation component of our world-class health system.

Introduced in 1948, the PBS has been, and continues to be, the cornerstone of Australia's modern health system, along with the National Medicines Policy (NMP). Australians receive universal, subsidised access to the latest prescription medicines and vaccines used to fight complex and debilitating ailments and improve quality of life and productivity. These include serious conditions that are rising in incidence in Australia such as diabetes, depression, dementia and cancer.

There are wide-ranging reasons the overall cost of the PBS has fluctuated over time. Sometimes variations in PBS expenditure have occurred because of changes in our population or more opportunities to tackle diseases in order to improve quality of life for Australians.

The operation and administration of the PBS is complex, involving multiple government agencies, manufacturers, wholesalers, prescribers, pharmacies and patients.

The innovative pharmaceutical industry works in partnership with the Australian Government in order to ensure the ongoing sustainability of the PBS.

Part of this partnership arrangement operates in practice through confidential pricing arrangements that include rebates. In some cases medicines are listed under risk-sharing agreements, whereby companies pay back all or part of any expenditure over an agreed amount to the Government. This ensures that expenditure through the PBS is sustainable, allowing both manufacturers and the Government to confidently plan for the future.

As seen in the graph overleaf, the listing by Government of Hepatitis C medicines saw a temporary increase in PBS expenditure. This increase is short term and does not include confidential rebates expected to be returned to Government on initial expenditure. These should be factored into growth projections of the PBS. Industry has significant special pricing arrangements and rebates that will mean that the 'headline' level of Government expenditure on PBS is substantially reduced.

By providing effective treatment and cure for this debilitating condition, cost pressure on more expensive treatment in the public and private hospital settings will also be reduced.

The broad expense categories in the Australian Government's Budget Papers No. 1 & 2 have remained almost unchanged for the past 15 years. With respect to health expenses, there are a handful of 'subcategories' for PBS expenditure. In contrast, the Department of Health's Portfolio Budget Statement has gone through numerous changes over the same period of time.

## IMPROVE THE QUALITY OF REPORTING ON PBS BUDGET EXPENDITURE:

### ACTION 3

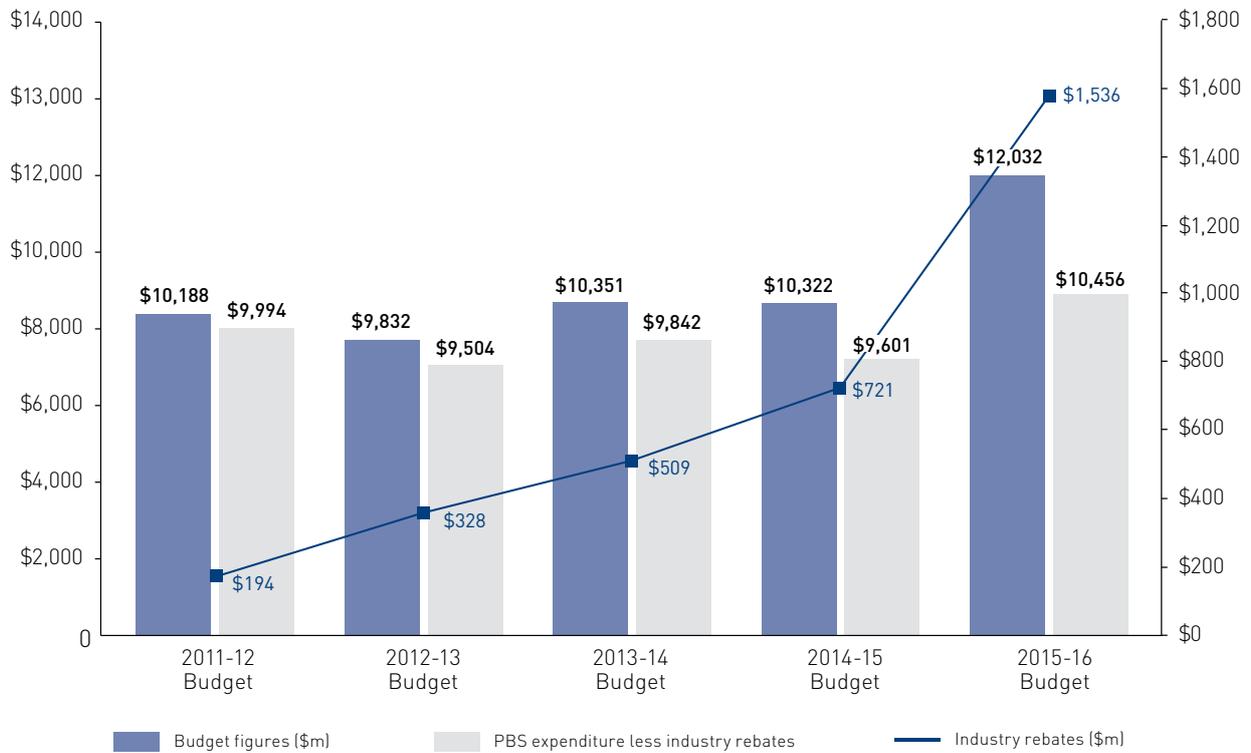
Publish headline PBS expenditure (excluding rebates) and net PBS expenditure (including manufacturer rebates to Government).

### ACTION 4

Report PBS expenditure against outcomes for different areas of the supply chain, in order to make information about changes over time more transparent.

## FIGURE 1 - PBS AND RELATED SERVICES EXPENDITURE

Expenditure on PBS and related services growth compared to industry rebates (\$m)



Growth in budgeted expenditure on PBS has been just over 18% over recent years (as demonstrated in the graph above) while the growth in the rebate from industry to the Government has increased by 692% over the same period.

While changes of this nature sometimes result in better presentation of information for the budget year, it can also make it much harder for observers to track and analyse changes in expenditure over time.

The number of 'outcomes' in the Portfolio Budget Statements (which the Department of Health reports against for the purpose of monitoring major areas of spending) has increased from 11 in the 2005/2006 Budget to 28 in the 2016/17 Budget.

Despite this, the outcomes for reporting on PBS expenditure have not evolved to keep pace with significant reforms compared to previous budgets.

Currently, 'headline' PBS expenditure is reported in annual reports and in budget documents, but the net cost of the PBS is not at all clear. The best outcomes in public policy emerge when the process is open, accountable, and transparent.



# BUSINESS ENVIRONMENT

The Australian pharmaceutical industry requires predictability and stability in policy settings, along with timely reimbursement for medicines and vaccines. Funding stability through the PBS helps the industry bring new treatments to patients and consumers.

**A sustainable and stable PBS is key to continued investment in innovation in the pharmaceutical industry. Any changes to the PBS must recognise the long-term nature of the industry's investment in innovation.**

There has been a recent shift, with individual expenditure on medicines outside of the PBS now exceeding the amount individuals pay for subsidised pharmaceuticals through the PBS.<sup>2</sup>

Many cost-saving initiatives implemented by the Government have a delayed impact on the PBS.

The reforms introduced by Government in recent years have continued to deliver higher than expected savings. This continues to create uncertainty for the industry as there has been instability in the forecasts of how much the Government is willing to commit to future expenditure on innovative medicines.

Australian Government spending on PBS medicines as a proportion of GDP is around 0.72%, and has stabilised over the past few years as industry has worked with Government. The 2007, 2010 and 2016 reforms coupled with price disclosure in 2013 have achieved savings in excess of \$20 billion in 2017–18. Following these reforms, PBS expenditure excluding payments to related services has been flat.

The industry welcomes the MMDR regulatory reforms announced in September 2016. These reforms will help speed the time to registration approvals for certain medicines and align well with developments in technology. The TGA is charged with implementing these significant and important reforms. It will be important to ensure that the TGA technology systems can support the revised regulatory processes needed to accelerate medicines access.

<sup>2</sup> Australian Institute of Health and Welfare, 2016. Health Expenditure Australia 2014–15. For 2014–15, average individual recurrent health expenditure per person for Benefit-paid pharmaceuticals is \$64, and for all other medications, \$395.

## BOLSTER BUSINESS CONFIDENCE IN THE INDUSTRY:

### ✓ ACTION 5

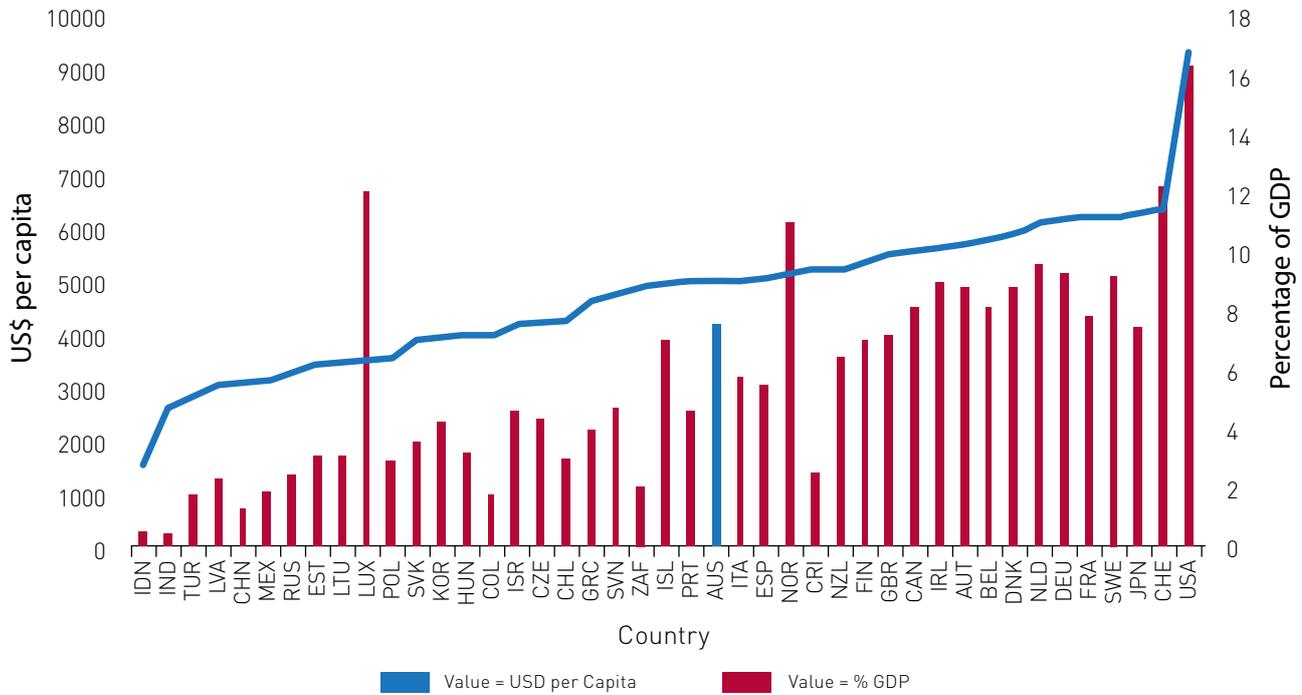
Ensure a sustained period of policy stability and predictability.

### ✓ ACTION 6

Provide systems support to enable smooth implementation of the MMDR reforms by the TGA.

## FIGURE 2 - HEALTH SPENDING FOR OECD COUNTRIES, 2014

Source: OECD Statistics



As shown in Figure 2 above, compared with other countries in the OECD, Australia spends just under the OECD average on health as a percentage of GDP. This highlights that current expenditure is effective in contributing to a world-class health system, but that there are opportunities for further improvements.

# INVESTMENT

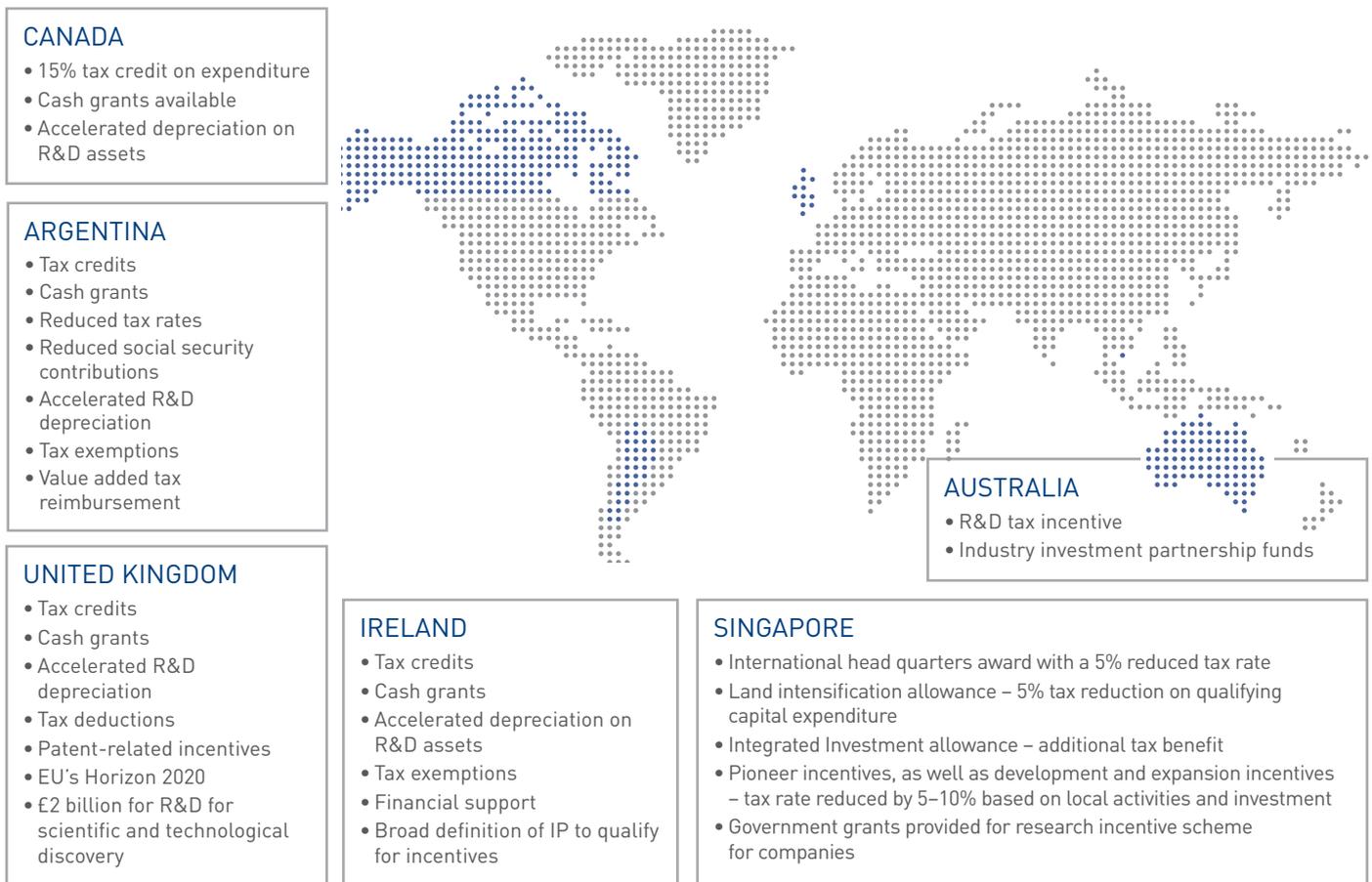
Pharmaceuticals and vaccines are a significant advanced manufacturing export market for Australia.

There are exciting opportunities for Australia to grow its share of the international pharmaceutical trade, with global demand for medicines expected to double in a decade. 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.

Currently, Australia exports about \$3 billion of vaccines and medicines.

**FIGURE 3 – INTERNATIONAL COMPETITORS' INCENTIVES FOR ADVANCED MANUFACTURING AND R&D<sup>3,4</sup>**



Source: Adapted from <sup>3</sup>EY, 2013-2014 Worldwide R&D incentives reference guide, and <sup>4</sup>Singapore Government, Incentives for businesses.

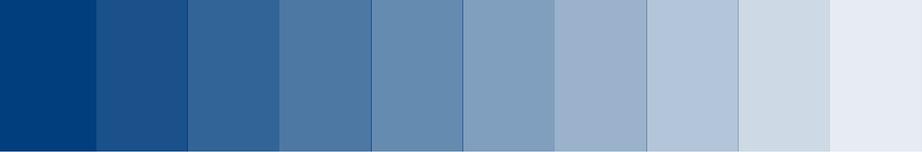
## ENCOURAGE INVESTMENT AND BOOST COMPETITIVENESS:

### ACTION 7

Introduce zero interest loans for advanced manufacturing facilities built in Australia.

### ACTION 8

Continue the MTPConnect Project Funding Programme.



Our aim is to work with the Government to build Australia's commercialisation capability at all stages of medicines and vaccines development, which will benefit both the economy and patients.

As Figure 3 demonstrates, our major international competitors have a range of incentives in place in order to attract investment, including tax credits, grants, loans and exemptions.

MTPConnect has 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 of these funds will have a positive impact on the sector and should be continued, but there is a long lead time before the benefits of this investment will flow through to commercial opportunities.

As part of these efforts, we look forward to realising a new vision of pharmaceutical R&D in Australia, to attract new investments to this country. 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 incentives such as grants, loans and procurement-linked support schemes.<sup>5</sup> It has been recommended that the Australian Government rebalance support for business R&D through targeted reforms to better target R&D priorities, which is being given consideration.

As previously detailed in *Medicines Australia's Issues Briefing for the 45th Parliament*, for over 30 years the Australian Government set aside industry funding for the pharmaceuticals sector to support manufacturing. 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.

<sup>5</sup>Australian Chief Scientist, Submission to Inquiry into Australia's Future in Research and Innovation Joint Select Committee on Trade and Investment Growth



# INNOVATION

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 for the MTPConnect and the 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 for the innovative pharmaceutical industry. Research activities occur in publicly-funded research organisations, private research organisations, universities, and innovation-oriented businesses.

Overall, research into clinical medicine and vaccines sees Australia performing well above the world average.

Australia's extraordinary talent has enabled the development of ground-breaking discoveries. 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.<sup>6</sup>

Medicines Australia member companies are leaders in commercialisation of research and investment in innovation, as highlighted in the case study 2. The establishment of the MRFF provides Australia with the chance to become the world-leader in medical research.

<sup>6</sup>Organisation for Economic Co-operation and Development 2015. OECD Health Statistics 2015.

It will help to attract some of the world's best scientists, researchers and healthcare professionals to Australia.

Medicines Australia has proposed the creation of a "Centre of Excellence" to compliment the work of the MRFF and focus on the translation and commercialisation of medical research for new medicines. Building on the work being undertaken in the Bridge Program partnership with MTPConnect, the centre would strengthen the relationship between public agencies responsible for research, universities and research institutes with industry. This centre would be integrated as part of the National Research Infrastructure plan.

## CASE STUDY 2 - COLLABORATION AND INVESTMENT IN AUSTRALIAN INNOVATION

Novartis entered into an agreement to acquire Spinifex, an Australian-based company in June 2015. Spinifex was a company created by the University of Queensland and focused on the development of a peripheral approach to the treatment of neuropathic pain. With up to 8% of the adult population suffering from chronic neuropathic pain, and approximately 40% of patients not responding to current treatment, the development channels being undertaken by the partnership could help to address a high unmet medical need. Novartis purchased Spinifex for \$260 million plus additional agreed milestone payments and royalties. Should the innovative treatment become a commercial product for patients, it will be one of the largest deals ever signed between an Australian biotechnology company, a university and a global pharmaceutical company.

## ESTABLISH A CENTRE OF EXCELLENCE TO:

### ✓ ACTION 9

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 help to translate outcomes of investing in basic research, encourage more clinical trials and help to bridge the valley of death for commercialisation.

# CLINICAL TRIALS

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 pharmaceutical 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 and hampering its potential to attract clinical trials. Numerous reports at all levels of government have noted this problem for many years.

**Streamlining and harmonising ethics and research governance approvals, will enhance Australia's international competitiveness.**

The Australian Government is taking a national leadership role to reorganise the existing regulation of clinical trials within 12 months. Medicines Australia supports efforts to create a one-stop-shop for initiation of clinical trial sites, in particular when these sites are across multiple states.

Once this national coordination centre has been established, the Government could scope the benefits of expanding the role of this centre into a Centre for Clinical Trials. A Centre of Clinical Trials could drive better quality standards as well as help businesses (small, medium and large) to navigate through the different State/Territories systems for clinical trials, particularly ethics and research governance approvals.

Better coordination and data sharing arrangements are also needed to take advantage of the significant opportunities to accelerate the development of new technologies and treatments, as highlighted in the draft 2016 National Research Infrastructure Roadmap, by Australia's Chief Scientist Dr Alan Finkel.

Developing a de-identified dataset of health records would help meet the needs of researchers, clinical trial sponsors and healthcare providers would help research efforts and assist in identifying health trends.

As well as reforms to the regulatory environment and data sharing arrangements, with respect to clinical trials, a long-term plan that includes identification of how best to market Australia to potential investors could complement the MTPConnect plan currently under development. It could help to improve Australia's brand and promote our world-class capabilities for clinical trials in key markets through our existing trade teams. This strategy would be based on policies that support further clinical trial investment, through a simple, consistent approvals framework, and incentives to commercialise.

## ENHANCE CLINICAL TRIAL CAPABILITIES:

### ACTION 10

Continue to market clinical trials overseas, building on Australia's reputation as a great destination for investment.

### ACTION 11

Prioritise a national central point of contact to harmonise clinical trials regulation by working with the States and Territories.

### ACTION 12

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



# INTELLECTUAL PROPERTY

Pharmaceutical products have high development costs and high failure rates, which require long payback sales periods to recoup.

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 lower than comparable innovation and investment driven systems in other OECD countries with whom we compete.

The Australian Government aspires to make Australia a more innovative country with an economy driven by inventive, research-driven, knowledge-based industries. If the Government is to fulfil its agenda to increase Australian-based science and innovation, it must ensure that, at the very least, it maintains the current patent and data exclusivity provisions and should further explore improvements to the IP system.

Other comparable jurisdictions have stronger protections for data exclusivity, and Australia should be looking to align to these systems that support innovation. Countries such as New Zealand have begun to implement the intellectual property components of recent trade deals, such as the Trans-Pacific Partnership (TPP), and Australia should follow suit, or risk falling behind.

An important first step would be a forum for representatives from the biotechnology and pharmaceutical industry to discuss these opportunities with Government. An industry working party comprising representatives from the innovative medicines industry, biotechnology, health medical research, and generic and biosimilars sectors could be convened. The purpose of this forum, possibly coordinated by MTPConnect, would be to provide expert advice on the challenges and benefits to Australia arising from changes to IP arrangements.

## TO REMAIN COMPETITIVE THE GOVERNMENT SHOULD:

### ✓ ACTION 13

Acknowledge the agreement contained in the recent Trans Pacific Partnership to increase data exclusivity to eight years.

### ✓ ACTION 14

Ensure 15 years' effective patent life is realised for innovative medicines.

### ✓ ACTION 15

Establish a time-limited industry working party, to model the benefits to the economy and any challenges of implementing eight years' data exclusivity in Australia.



# EMPLOYMENT and SKILLS

As the Australian Government has identified, transitioning from an economy dependent on resource 'booms' to a more diversified economy will rely on job creation in more knowledge intensive sectors.

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. The reduction of payroll taxes for STEM graduates will provide a tangible incentive for companies, and will form part of the competitive localisation package offered by States and Territories for businesses to invest in their state.

To strengthen our life sciences industry, Australia needs to ensure we have the right incentives in place that can help us retain our best and brightest scientists.

## KICKSTART THE STEM ECONOMY:

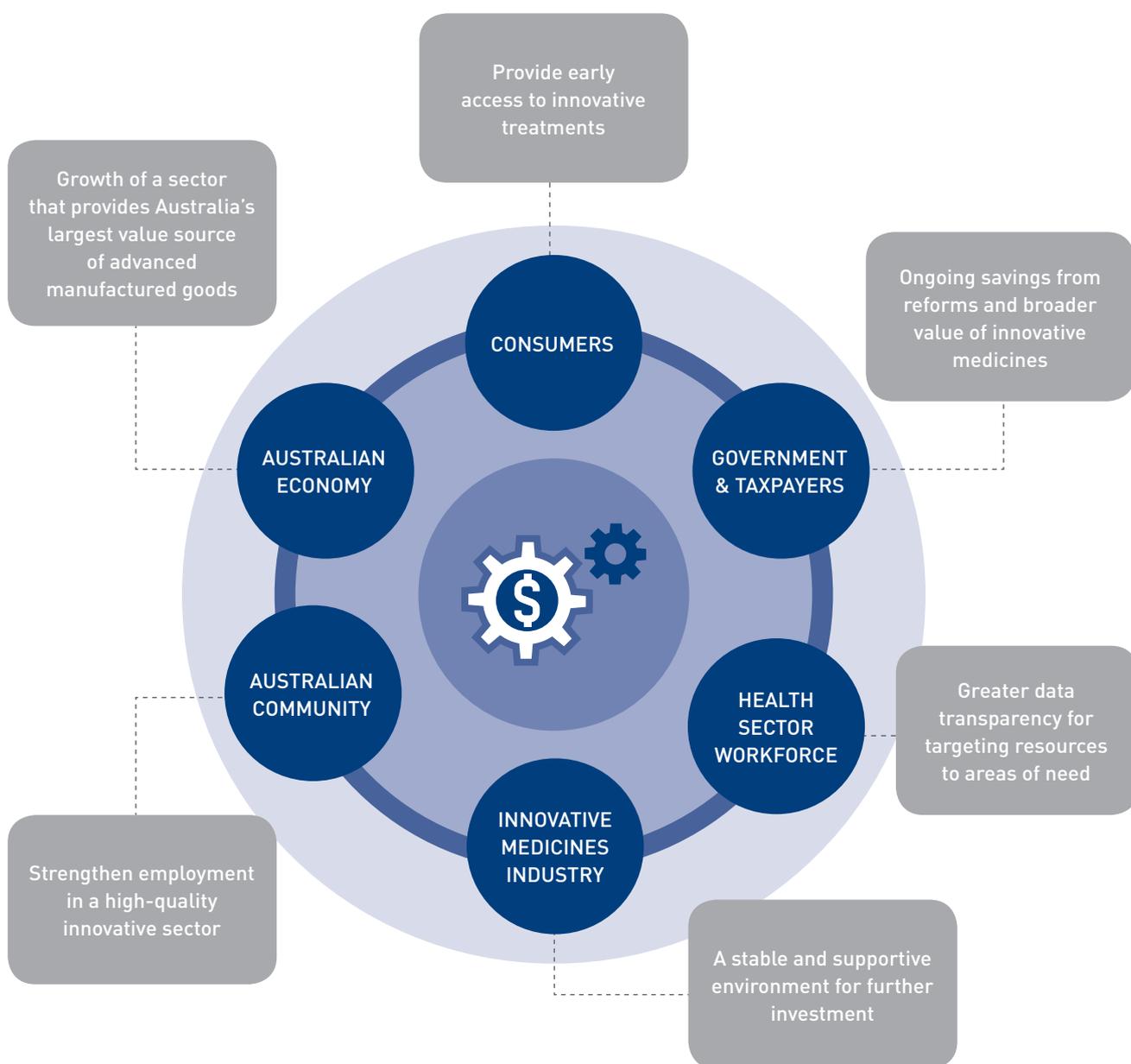
### ✓ ACTION 16

For STEM graduates, work with State and Territory governments to reduce payroll taxes.

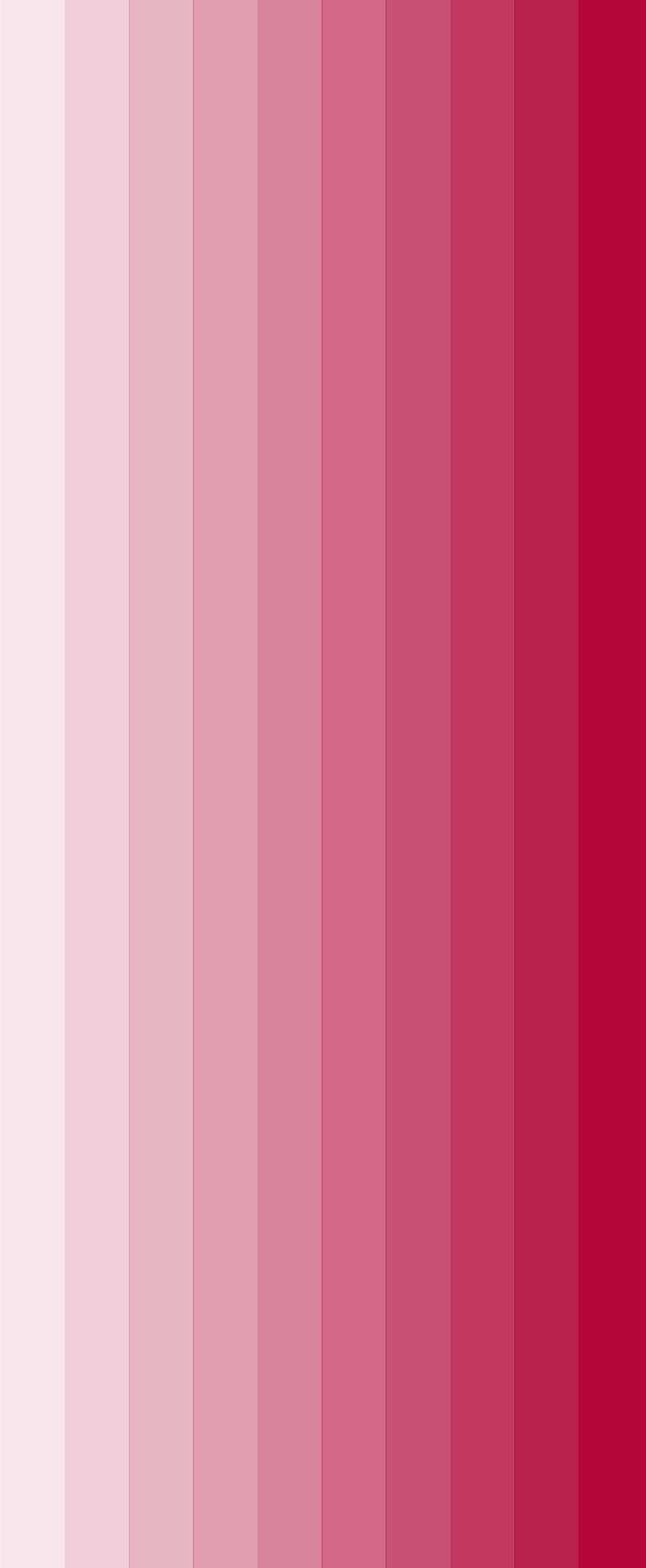
# SUMMARY

There are a range of benefits to be gained by introducing these policy changes in the 2017/18 Federal Budget and many are cost neutral or would have only a nominal budget impact.

These actions would help the Australian medicines industry to grow over the long term and encourage greater commercialisation of research. They would also help ensure that Australian patients would continue to benefit from receiving world-class innovative therapies.



MEDICINES  
*Australia*

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