

# MEDICINES *Australia*

Issues Brief

**3 Business  
Environment**

## CREATING THE EXTRAORDINARY TALENT OF TOMORROW

The medicines industry fosters extraordinary talent which translates promising scientific research into new treatments.

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





## OBJECTIVES BRIEF 3: BUSINESS ENVIRONMENT

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Medicines Australia strongly supports the Australian Government implementing the following measures:

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Maintaining stable and predictable policies for the Pharmaceutical Benefits Scheme (PBS) so that both patients and the medicines industry can effectively plan for the future.

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Encourage greater investment in Australia's medical technology and pharmaceuticals sector through fiscal measures such as tax concessions and other targeted incentives.



Restore targeted forms of funding for business R&D through a long-term plan for the medicines industry.

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Continue to reduce the regulatory burden on business.



# OVERVIEW

Medicines Australia member companies have continued to invest in Australia, even when many larger companies are closing major R&D centres in other parts of the world.

For the last several years, the innovative medicines industry has been under constant pressure to introduce new products in an environment of increasing R&D costs and growing global competition.

The Australian medicines industry also faces a progressively competitive international investment environment and mounting compliance pressures.

Despite these challenges, Medicines Australia member companies have continued to invest in Australia, even when many larger companies are closing major R&D centres in other parts of the world.

Contract research organisations (CROs) now play a much larger role in drug research and development activities worldwide; including development of research models, chemical and biological analyses, and clinical trial services at all stages of development.

As a consequence of the globalisation of the medicines industry and greater outsourcing arrangements the R&D landscape has substantially changed over recent years.

Member companies (often directed via regional or global headquarters) are more frequently entering into partnerships with research institutions or local health care clinics to undertake R&D activities.

Partnership agreements can significantly benefit the Australian economy, such as the agreement between Genea and Merck Serono outlined on the next page.





## CASE STUDY: GENEA AND MERCK FERTILITY COLLABORATION AGREEMENT

In May 2016, Australian fertility innovator Genea Biomedx reached a global collaboration agreement with Merck Serono (Merck Group) to create a unique approach to fertility treatment. Merck Group is an innovative, global healthcare leader focussed on improving health and well-being. Headquartered in Germany this company employs around 68,000 people.

Genea Biomedx's parent company Genea has long been a leader in the research and development of fertility science and has clinics across Australia as well as overseas.

The collaboration between Genea Biomedx and Merck Serono, the biopharmaceutical business of Merck Group, will build on their existing fertility heritage to create and deliver innovative solutions to Assisted Reproductive Treatment (ART) clinics and, in turn drive better outcomes for patients. It will also help deliver on Genea's strategy to grow into a company with broad global reach.

We need to be continually mindful of changes that are happening within the business environment globally. Changes to fiscal policies both here in Australia and in our closest trading partners have a major influence on product and services demand and thereby the future skills demand in the Australian workplace.



# CHALLENGE: RECENT REFORMS TO THE PBS HAVE IMPACTED ON THE MEDICINES INDUSTRY

The Pharmaceutical Benefits Scheme (PBS) has been substantially reformed over several years to create efficiencies and deliver enduring savings mechanisms for the Australian government. This provides capacity to list new innovative medicines and enables predictable, sustainable expenditure forecasts. Consequently, a sustained period of policy stability and predictability is needed to bolster business confidence in the innovative medicines sector.

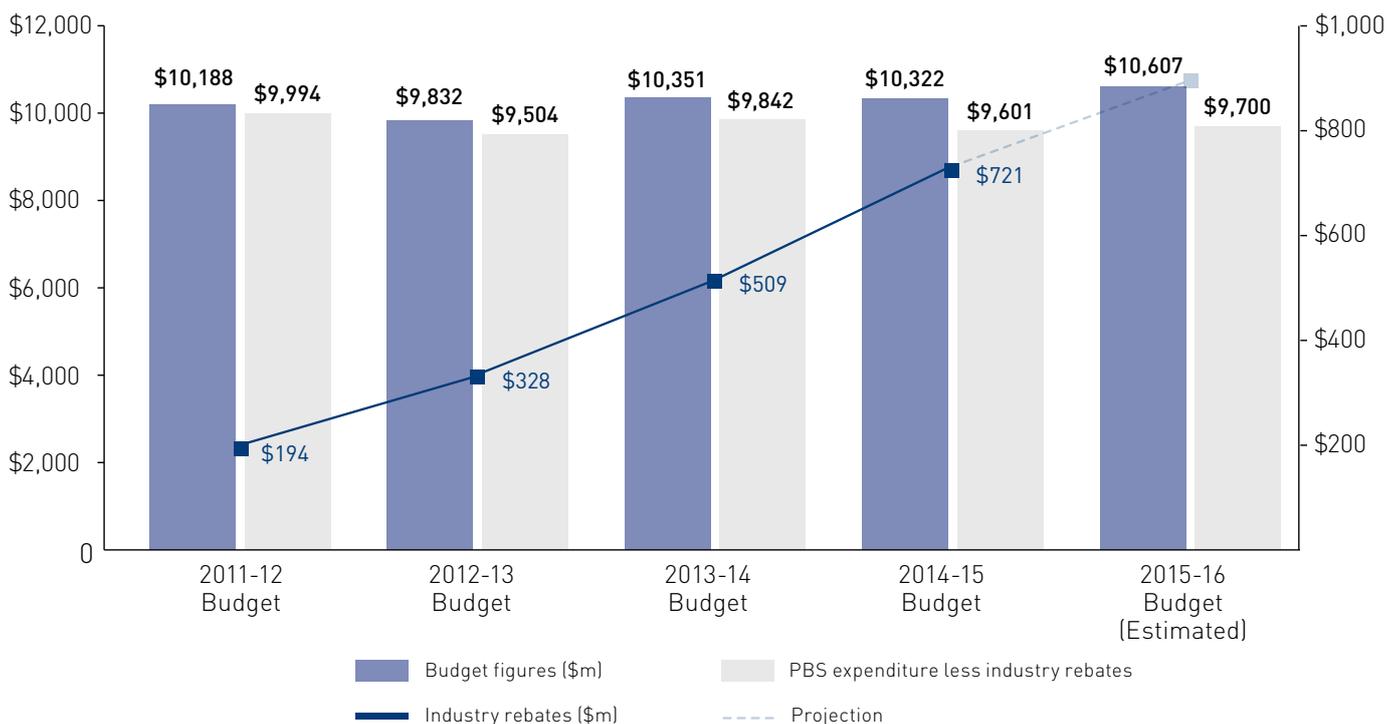
Medicines Australia acknowledges the fiscal challenges facing Government, and seeks to continue partnering with the Australian Government. The 2007 and 2010 PBS reforms coupled with the introduction of Simplified Price Disclosure in 2013 have achieved savings in excess of \$20 billion to 2017-18.<sup>1</sup> In addition, in May 2015 the Australian Government announced \$6.6 billion additional savings (\$3.7 billion net) as part of the 6th Community Pharmacy Agreement and PBS Access and Sustainability Package (PASP).

The 2015 Mid-Year Economic Fiscal Outlook (MYEFO) update showed higher than expected savings from existing pricing policies, with \$549 million in reduced PBS payments. This reduction is expected to be up to \$1.6 billion over 4 years to 2018-19. In addition, PBS agreements with pharmaceutical companies sometimes include rebates to Government which help to ensure expenditure remains sustainable after a new medicine is listed.

After these reforms, PBS expenditure excluding payments to related services has been flat, with the five year growth being just 2.2% (Figure 1). Given that this level of growth is below inflation, it appears certain that the long-term PBS expenditure trajectory is on a sustainable path.

1. Victoria University, Centre for Strategic Economic Studies, the impact of further PBS reforms, May 2013. Available at: <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20130515-rep-The-Impact-of-Further-PBS-Reforms-Final-report-from-CSES.pdf>

**FIGURE 1: SUSTAINABLE PBS EXPENDITURE**



# SOLUTION: PREDICTABILITY IN THE PBS HELPS TO ENCOURAGE INVESTMENT AND GUARANTEE JOBS

Medicines companies require very long lead times to adapt to changes in Australian Government policy. Policy changes should be gradual and implemented carefully and incrementally to ensure there are no unintended consequences. The evolution of PBS policy over the last few decades demonstrates the merits of a collaborative approach to policy change versus an ad hoc, piecemeal approach.

Where changes were negotiated through collaboration, effective reforms were introduced and disruption to the industry, patients and government was minimised. Stability in the business environment allows medicines companies, their employees and partner organisations to effectively plan for and adapt to the future.

## Medicines Australia welcomes the Australian Government's commitment to

“ ensuring that the Pharmaceutical Benefits Scheme (PBS) provides Australian patients with affordable access to pharmaceuticals including new, innovative and expensive medicines which have been independently assessed as safe, effective and cost-efficient. We are conscious of the need to balance patient care with the long-term sustainability of the scheme while ensuring that pharmaceutical companies receive a reasonable return on their risk and investment.”<sup>2</sup>

2. Liberal Party of Australia, Coalition response to Medicines Australia Federal Election Questionnaire, June 2016, unpublished

# CHALLENGE : MAINTAINING A COMPETITIVE, SUSTAINABLE AND PREDICTABLE TAX SYSTEM

## Government direct R&D incentives include

grants, loans and procurement.

## Government indirect R&D schemes include

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

A competitive tax system and stable policy settings are vital for Australia to attract investment. Investment in R&D, clinical trials of new medicines and growth in advanced manufacturing will enhance the industry's ability to create jobs and capitalise on opportunities to grow export markets. All of this would augment economic activity, improve productivity and ultimately generate higher tax revenues for Australia.

As noted in Organization for Economic Cooperation and Development (OECD) data, R&D incentives continue to evolve at a rapid pace worldwide. As countries continue to reform their R&D schemes some are making their incentives more generous while others are targeting their funds more closely.

In Australia the R&D tax incentive programme is the largest source of indirect support for business R&D. It has a number of strengths in comparison to schemes in other countries. According to the **EY worldwide R&D tax incentive guide** key features of the scheme include:

- Offsets for wages and salaries associated with business R&D activities; and
- Payments made by medicines companies to contract research organisations (generally eligible).

Eligible companies can include foreign companies operating in countries that have a double taxation treaty with Australia when carrying on business through a permanent establishment in Australia.

In recent years the R&D tax incentive has been the subject of a series of reviews and ongoing changes. As part of the **National Innovation and Science Agenda (NISA) Statement** a further review of the R&D tax incentive was commissioned, led by Bill Ferris (the Chair of Innovation Australia), Dr Alan Finkel (Australia's Chief Scientist) and John Fraser (the Secretary of the Treasury). The main purpose of the review is to evaluate the effectiveness and integrity of the current arrangements for supporting business R&D and the level of additionality they stimulate.



Australia's Chief Scientist states that there is a need for the Australian Government to invest directly and indirectly in business R&D.

An R&D tax incentive review issues paper has highlighted the following key challenges:<sup>3</sup>

**1. Budget costs of the R&D tax concession and R&D tax incentive schemes have risen strongly**

Originally costing \$2.5 billion in 2011–12, R&D expenditure is forecast to grow further to around \$3.5 billion by 2017–18. The actual cost has been significantly higher than originally forecast, largely due to growth in the cost of the refundable components for businesses with a turnover of less than \$20 million.

**2. Changes to the expenditure claim threshold of \$100 million**

While limiting the cost of the programme to some extent, this change has also removed the incentive for firms to undertake additional R&D in Australia beyond that threshold.

**3. Business-as-usual activities being claimed instead of R&D activities**

Under the tax incentive concession scheme there was some evidence that business as usual activities were being claimed rather than activities associated with core R&D activities.

**4. Multiple federal agencies responsible for the administration of the R&D tax incentive**

Different agencies responsible for promotion, industry education, registration and determination of eligibility of R&D activities.

Australia's Chief Scientist states that there is a need for the Australian Government to invest directly and indirectly in business R&D.<sup>4</sup> The Medicines Australia Issues Brief on Innovation (no. 5) covers a number of other targeted measures to support R&D, such as grants administered by the NHMRC and other agencies.

The Australian Government's **Ten Year Enterprise Tax Plan** also aims to support economic success, attract new investment and create jobs.<sup>5</sup> Specifically, this plan claims to support growth, higher wages and jobs by lowering the tax rate for companies over time to an internationally competitive level.

Under the plan, the company tax rate will be progressively lowered to 25% firstly for small businesses and will include all companies by 2026–27. In addition, the Australian Government has announced new measures to protect Australia's tax base, enforce compliance and provide greater levels of transparency.<sup>6</sup>

3. R&D Tax Incentive Review Issues Paper, Australian Government, 2016

4. Australia's Chief Scientist, Q & A at the National Press Club, March 2016. Available at: <http://www.chiefscientist.gov.au/2016/03/qa-at-the-national-press-club/>

5. Liberal party of Australia, Jobs and Growth Budget 2016, May 2016. Available at: <http://budget.liberal.org.au/smallbusiness.html>

6. Liberal party of Australia, Jobs and Growth Budget 2016, May 2016. Available at: <http://budget.liberal.org.au/multinationals.html>

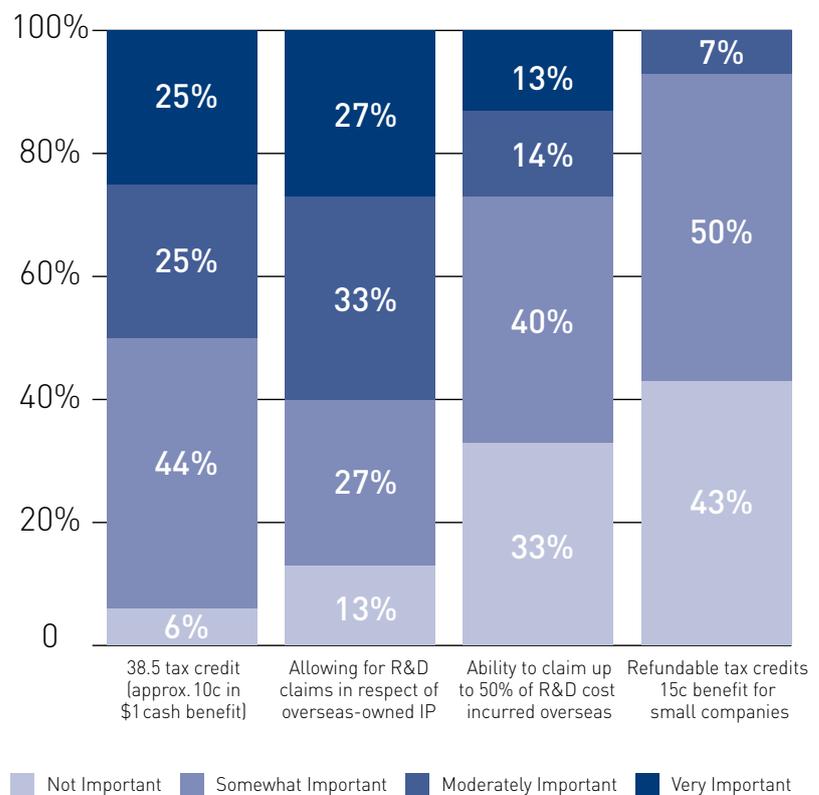
# SOLUTION: OPTIMISING TAX INCENTIVES SO THEY ARE COMPETITIVE AND SUSTAINABLE

Thousands of jobs for Australia’s future scientists, researchers and clinicians will rely on which R&D incentives are viewed as valuable by policy makers.

Medicines Australia represents 25 of 27 of the largest medicines companies in the world as well as many small to medium sized enterprises (SMEs). Medicines Australia supports the view that R&D incentives should aim to encourage businesses of all sizes, and does not support inequity in incentives.

A PWC report on the Australian Pharmaceutical Industry (2014) examined what medicines companies valued most about the R&D tax credit programme. Compared with global incentives, half thought Australian incentives were less competitive and half thought they were generally equivalent. Many medicines companies expressed that R&D tax credit would be more compelling if available “above the line”.

**FIGURE 2: IN 2014, WHAT DO YOU VALUE MOST ABOUT THE GOVERNMENT’S CURRENT R&D TAX CREDIT PROGRAM?**



Source: PWC, Challenges and Change: A report on the Australian pharmaceutical industry, 2015. <http://www.pwc.com.au/industry/healthcare/assets/challenges-and-changes-final.pdf>

Figure 2 demonstrates that what medicines companies overwhelmingly value most about the current R&D scheme is the allowance for R&D claims in respect of IP ownership. Medicines Australia’s Issues Brief on Intellectual Property (no. 7) provides further detail on why stable IP settings are of crucial importance to our innovative medicines industry.

On average,  
it costs between  
\$1.5–2.6 billion  
to develop a new  
medicine over a  
10–15 year period.<sup>7,8</sup>

Given the substantial amount of capital and long-term investment needed to develop medicines, engaging larger organisations in R&D is critical. Medicines Australia Issues Brief on Clinical Trials (no. 6) provides further detail on the high costs in Australia.

Australian Bureau of Statistics data reveals that the majority of R&D activity is currently occurring in businesses at the larger end of the spectrum. Larger businesses are therefore critically important engines that drive R&D and contribute to the overall growth of our economy.

The **Group of Eight (G8)**, the peak body representing the interests of our research intensive universities, suggest that R&D tax concessions need to take into account the cost of conducting such activities onshore compared to competitor countries. The G8 conclude that while our lack of competitiveness is acting as a deterrent to large multinational organisations choosing to invest here, adjustments to our current taxation system could help to address this.

Many thousands of prospective jobs for Australia's future scientists, researchers and clinicians will rely on how ongoing arrangements for R&D incentives are to be administered.

The Australian Government may assist by:

- Adopting a more nuanced approach that helps all areas of the medicines industry, regardless of size;
- Improving administrative arrangements for the R&D tax incentive scheme to help build Australia's R&D capacity; and
- Considering more targeted measures such as grants to support business R&D (as part of a long-term plan for the medicines industry).

In addition to R&D tax incentives and a reduction to the company tax rate, a number of recent proposals also open the way for a broader discussion on new tax incentives. For instance, the introduction of an advanced manufacturing incentive was suggested in the last parliament by the **Joint Select Committee on Trade and Investment** following inquiry into Australia's Future in Research and Innovation.<sup>9</sup> Suggestions arising as a result of this inquiry have been recommended for Treasury to review.

Medicines Australia notes both of the major political parties will consider the recommendations arising from the review of R&D incentives. Medicines Australia looks forward to further consultation with Parliamentarians on how future R&D schemes can better deliver on our shared objectives of encouraging greater innovation through industry investment.

Where there are disagreements between political parties over tax reform, sensible compromises should be reached to ensure a stable business environment in Australia. Predictability and certainty in tax arrangements allow our member companies to effectively plan for the future, to make investment decisions and most importantly guarantee jobs.

7. Mestre-Ferrandiz, J., Sussex, J. and Towse, A. [2012] The R&D Cost of a New Medicine. Office of Health Economics. Available at: <https://www.ohe.org/publications/rd-cost-new-medicine>

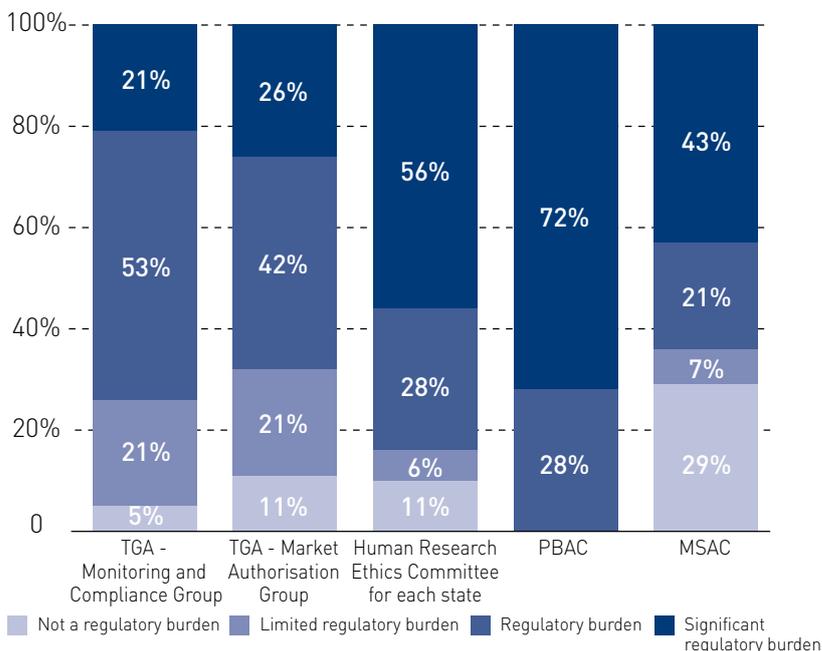
8. DiMasi JA, Grabowski HG, Hansen RA. Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of Health Economics* 2016;47:20-33.

9. Inquiry into Australia's Future in Research and Innovation, Report of 3 May 2016. Available at: [http://www.aph.gov.au/Parliamentary\\_Business/Committees/Joint/Trade\\_and\\_Investment\\_Growth/Research\\_and\\_Innovation/Report](http://www.aph.gov.au/Parliamentary_Business/Committees/Joint/Trade_and_Investment_Growth/Research_and_Innovation/Report)

## CHALLENGE: REGULATORY BURDENS ARE INCREASING

Medicines companies say they are experiencing increased regulatory burden across many areas. Results from a 2014 industry survey demonstrate the main areas of concern.

**FIGURE 3: EXTENT OF REGULATORY BURDEN IN 2014**



Source: PWC, Challenges and Change: A report on the Australian pharmaceutical industry, 2015. <http://www.pwc.com.au/industry/healthcare/assets/challenges-a-and-changes-final.pdf>

The **Australian Government's Guide to Regulation**<sup>10</sup> highlights the need for policy makers to seek practical solutions, balancing risk with the need for regulatory frameworks that support a stronger, more productive and diverse economy where innovation, investment and jobs are created.

## SOLUTION: PRIORITISING MEASURES TO REDUCE THE REGULATORY BURDEN ON BUSINESS

A number of processes are underway that have the potential to significantly reduce the amount of red tape that most impacts the medicines industry. Medicines Australia particularly welcomes the \$20.4 million investment over four years in response to the TGA's Medicines and Medical Devices Review (MMDR) although at the time of publication specific details of what these changes would be or how they would be implemented had yet to be announced by the Australian Government. New measures are expected to provide industry with savings of around \$75 million per annum by removing or streamlining unnecessary or inefficient TGA processes. Further information is provided in Medicines Australia's Issues Brief on Access (no. 1).

The Australian Government has also made commitments to:

- Remove or streamline unnecessary or inefficient TGA processes;
- Harmonise the regulatory framework for clinical trials;
- Consider proposals to streamline intellectual property processes;<sup>11</sup>
- Consider proposals to streamline NHMRC grant processes; and
- Simplify the process Australian exporters need to follow in order to satisfy Australian Government export requirements.<sup>12</sup>

Medicines Australia welcomes these initiatives and looks forward to working with the Government to ensure these new measures are implemented as quickly as possible.

10. The Australian Government Guide to Regulation, Department of the Prime Minister and Cabinet, 2014. Available at: [https://www.cuttingredtape.gov.au/sites/default/files/files/Australian\\_Government\\_Guide\\_to\\_Regulation.pdf](https://www.cuttingredtape.gov.au/sites/default/files/files/Australian_Government_Guide_to_Regulation.pdf)

11. The Australian Government, IP Australia, 7 April 2015. Available at: <https://www.ipaustralia.gov.au/about-us/public-consultations/consulting-proposals-streamline-ip-processes-and-support-small>

12. Liberal Party of Australia, the Coalition's policy to develop Australia's Medical Research Capabilities, May 2015. Available at: <https://www.liberal.org.au/coalitions-policy-develop-australias-medical-research-capabilities>



Issues Brief

## 3 Business Environment

# EXECUTIVE SUMMARY

## A COMMON GOAL

Encourage investment in Australia by the medicines industry to secure growth in high-value employment.

## KEY CHALLENGES

- Several years of substantial reform to the Pharmaceutical Benefits Scheme has impacted on the medicines industry in Australia.
- A competitive, sustainable and predictable tax system is needed to encourage innovation in the medicines industry.
- The regulatory burden on business has increased in many areas.

## KEY SOLUTIONS

- A sustained period of policy stability and predictability is needed to help encourage growth and guarantee jobs.
- Refocus tax incentives to help build Australia's R&D capacity and encourage greater innovation through industry investment.
- Prioritise measures to reduce the regulatory burden on business, including streamlining of inefficient TGA processes and harmonisation of the regulatory framework for clinical trials.