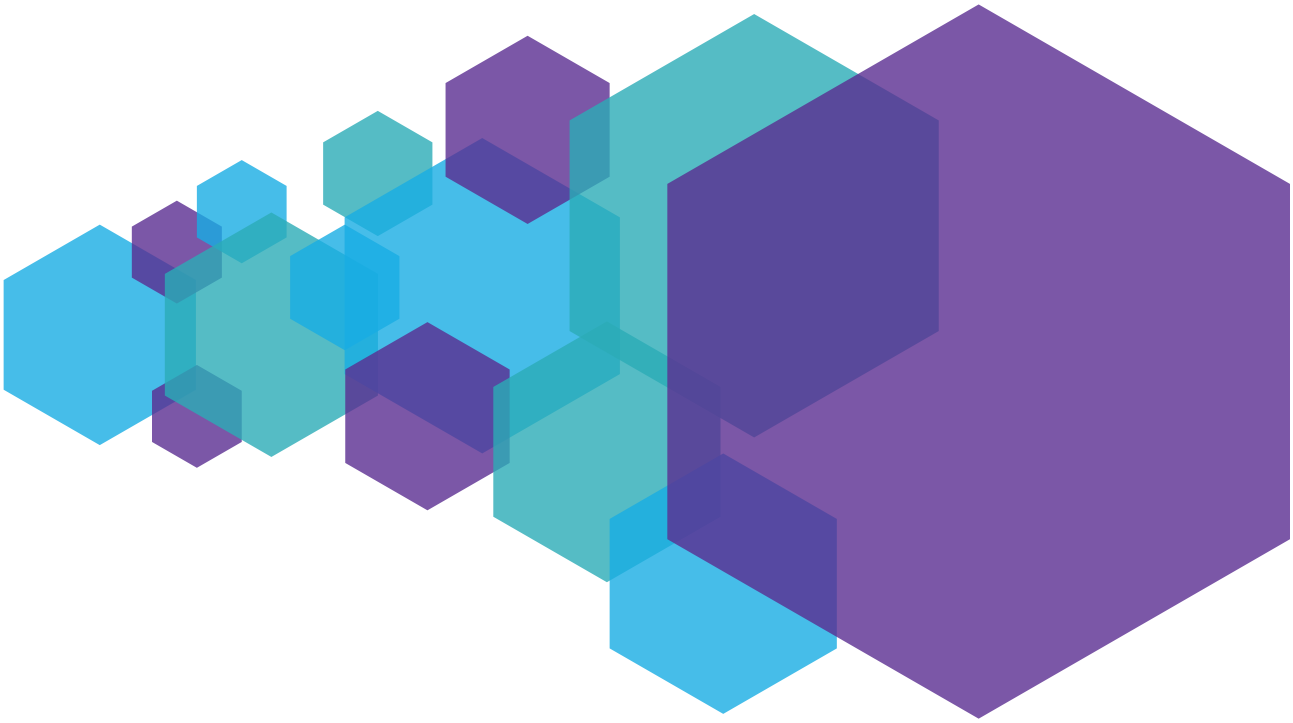
The economic contribution of the innovative pharmaceutical industry to Australia

Economic footprint of the innovative pharmaceutical industry

February 2018



Medicines Australia

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Report overview

The innovative pharmaceutical industry contributes to the health and economic prosperity of the nation. It provides new treatments to save and improve people's lives and also contributes to the Australian economy by undertaking business, research and manufacturing locally. The following are results from a survey, interviews and analysis conducted by PricewaterhouseCoopers Consulting (Australia) Pty Limited (PwC Consulting).

PwC Consulting estimated that the innovative pharmaceutical industry contributed **$8.9 billion to the Australian economy in 2016**, through direct, indirect and induced contributions. A major driver of contribution is the **22,900 FTE jobs** supported by the industry.

$8.9 billion
estimated contributed to the Australian economy in 2016 by the industry

22,900 FTE jobs
supported by the industry in 2016

The $8.9 billion contribution represents the impact from an economic perspective. There were also additional categories of contribution captured in the survey results including:

- **Local clinical trials which** provide access to innovative medicines for Australian patients, local high skilled training and development opportunities and the opportunity for the development of local intellectual property.

970
local clinical trials

$270 million
invested in local clinical trials

33,400 patients
gaining access to new medicines through clinical trials

- **Local manufacturing** which supports local jobs and businesses, provides surety of local supply and contributes to international trade.
- **Compassionate access schemes** provide patients free or discounted access to drugs that are not Pharmaceutical Benefits Scheme (PBS) listed which could be a last resort option for some patients.
- Companies invest considerably in these schemes through products and company resources to support supply.

$1.2 billion
produced in exports for five respondents

18,600
business relationships with suppliers

16 companies
provide compassionate access schemes

- **Collaborations or strategic partnerships** in Australia with a subset of twelve respondents having invested over $99 million in these relationships in 2016.

over $99 million
invested in collaborations

The business environment for the industry

The last two years were considered challenging for the innovative pharmaceutical sector. Almost all of the respondents were affected by pricing reforms in the last two years, with some having to implement considerable cost saving initiatives.

Many companies are **anticipating challenges to continue** into the future however there appears to be an overall positive shift in the business environment for the industry.

The majority of respondents noted an improvement in the perception of innovation and value of new medicines.

Total economic contribution and footprint

This chapter summarises the economic contribution findings from the survey analysis. The economic contribution is measured through direct, indirect and induced calculations and major drivers of value for these estimates include total employment, salaries and wages, revenue and operating profit for the industry.[1]

Economic contribution

The innovative pharmaceutical industry's contribution to the Australian economy is measured in three separate components for this report:

$8.9 billion

Estimated contributed of the industry **to the Australian economy in 2016**

- **Direct contribution** – measure of the direct contributions from the industry to the economy and GDP estimated in gross value added (GVA)[2]
- **Indirect contribution** – measure of the economic impact to suppliers for the goods and services that they provide to the industry
- **Induced contribution** – measure of the personal spending of workers employed directly and indirectly by the industry

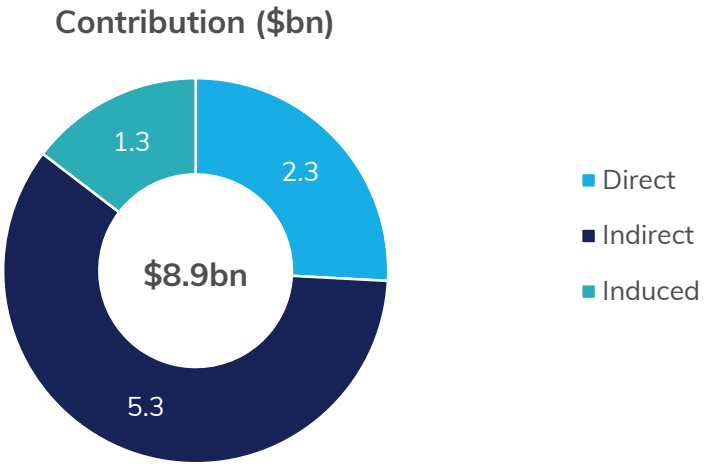
1 Further information on the economic analysis methodologies can be provided upon request to Medicines Australia.

2 GVA is a measure of the industry production value and the contribution to overall gross product and is considered a good estimate of economic contribution because it removes distortion caused by taxes and subsidies across different industries.

PwC Consulting estimated that the innovative pharmaceutical industry contributed **$8.9 billion to the Australian economy in 2016**. Results for the three components are shown in Figure 1. The industry had an estimated **$2.3 billion** in direct, **$5.3 billion** indirect and a further **$1.3 billion** in induced economic contributions for 2016.

The majority (90 per cent) of the total $8.9 billion in economic contribution is estimated from 33 surveyed Medicines Australia member company responses totalling $8.1 billion and the additional $800 million is based on responses or assumptions for innovative pharmaceutical companies that are not MA members.

Figure 1: Economic contribution of the innovative pharmaceutical industry (2016)

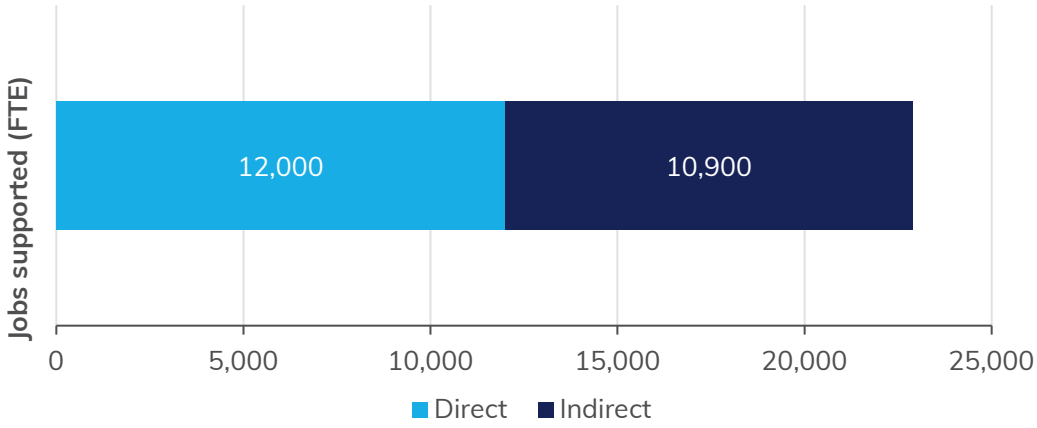


Source: Survey data, PwC Analysis

Jobs supported

In 2016 the pharmaceutical industry supported approximately **22,900 FTE jobs**. More than half of the estimate, or 12,000 FTE jobs are for roles that are directly employed by the industry with many for highly skilled positions. For the 12 companies that responded to the relevant survey question, over 80 per cent of their staff had a bachelor's degree or higher.

Figure 2: Jobs supported by the innovative pharmaceutical industry (2016)



Source: Survey data, PwC Analysis

Innovative pharmaceutical companies contributed $8.9 billion to the Australian economy in 2016. They also provided additional worthwhile benefits to society. The following are findings and examples of how the industry supports the Australian economy and society that are not directly included in the economic contribution estimates:

Provision of innovative medicines for Australia

The primary purpose of the pharmaceutical industry is to discover, research, manufacture and supply pharmaceutical products and services. It is extremely costly to develop new medicines that are effective and safe for patients with one report estimating an average cost of $USD 2.5 billion to bring a new prescription drug to market.[3]

It is estimated that over 80 per cent of the value of PBS listings are for innovative medicines produced by MA members.[4] Over 50 products were listed on the PBS in the last two years for 22 MA respondents, with companies estimating that over half of those new medicines addressed an unmet clinical need and 36 per cent were considered 'blockbusters'.

Fourteen of the survey respondents estimated that almost 10 million people in Australia are using their top five products (by market value) with clinical benefits such as reduced pain, increased quality of life, improved overall survival, management of chronic disease, prevention of stroke, decreased mortality and curing disease. Some of these top products are also estimated to provide additional benefits to patients and society such as through an earlier return to work, reduced carer costs, reduced disability payments and prevention or reduction of health care costs such as hospitalisations.

The clinical treatment value of medicines is estimated through health technology assessment (HTA) in Australia and is compensated by PBS reimbursement to companies for the supply of these medicines.
The potential impacts on patient productivity, carers and healthcare costs are however not necessarily captured in the standard HTA approach. These benefits can be substantial for some treatments considering a patient's ability to return to work earlier or at all, pay taxes and potentially avoid welfare payments.[5]

Finally, there is a large value-chain of businesses in Australia that benefit from the innovative pharmaceutical industry including generics companies, wholesalers and pharmacies. Without innovative medicines these organisations would not benefit as they do now.

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3 Mullin, R., 2014. 'Cost to develop new pharmaceutical drug now exceeds $2.5B'. Available from <https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/>.

4 MA analysis.

5 Schofield D, Shrestha R, Cunich M. (2016). Measuring labour productivity and the benefits of interventions for osteoarthritis. Please contact Medicines Australia for a copy

Clinical trials in Australia

Nineteen survey respondents stated that they carried out or invested in[6] local clinical trials and invested almost $270 million in 2016 to do so. These trials reached over 33,000 patients across approximately 970 trials.

Table 1: Respondent clinical trial totals in Australia (2016)

	Total (19 companies)
Number of clinical trials	970
Number of sites	4,200
Number of patients	33,360
Investment in value for 2015/16	$268.8 million

Source: Survey data, PwC Analysis

Clinical trial location details were provided by 10 respondents which show trial sites spread across 163 postcodes in Australia. The top five postcode locations with the most trials are listed in Table 2.

Based on the data collected, there is a direct link between the highest concentration of clinical trials by postcode and the location of some of Australia's universities and large hospitals.

Table 2: Top five postcodes for clinical trial sites (n=10)

Rank	Trials	Postcode	Location	State
1	80	2050	Camperdown	NSW
2	79	3004	Melbourne	VIC
3	76	2010	Surry Hills, Darlinghurst	NSW
4	71	6009	Nedlands, Crawley, Dalkeith	WA
5	69	3168	Clayton, Notting Hill	VIC

Source: Survey data, PwC Analysis

[6] Responses included investments for investigator led clinical trials.

Local clinical trials provide value to Australia in various ways including:

- Providing early access to innovative medications for Australian patients who may have no other options and may experience life changing results
- Offering employment and training opportunities for highly skilled (Science, Technology, Engineering and Mathematics – STEM) workers and helping attract international research talent and funding
- Developing intellectual property that can be globally licensed

Clinical trials offer employment and training opportunities to highly skilled STEM workers.

Based on the interview conversations conducted, Australia is generally considered to be a favourable country to conduct phase 2 and 3 clinical trials with high quality local expertise, clinical care and infrastructure. These factors are particularly important for more complex research areas such as neurology or oncology.

However, respondents stated that Australia is a relatively expensive market in which to conduct clinical trials and international competitiveness is growing each year with some countries offering bold incentives to attract future clinical trials.

A recent report on clinical trials in Australia from MTPConnect outlined the drivers and impediments for Australia's competitiveness to attract industry sponsored clinical trials:[7]

Drivers	Impediments
• Medical experts/research with global standing and experienced trial staff • Quality of local research capability and output • Rapid trial start up process: Therapeutic Goods Administration Clinical Trial Notification (CTN) scheme and streamlined ethics • Specialised and dedicated infrastructure • Comparable cost, including the value of the research & development tax incentive	• Complex site governance: individual site governance process is highly variable and requires further streamlining • Low participant recruitment numbers per site which in turn drives higher cost per patient • High trial cost for certain sub-sectors • A need to invest to develop capability in specialised, high risk and innovative trials to remain a leading trial destination

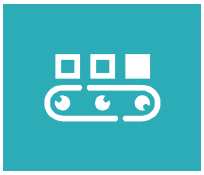
Source: MTPConnect Clinical Trials in Australia report

[7] MTPConnect, 2017. 'Clinical trials in Australia: the economic profile and competitive advantage of the sector'. Available from <https://www.mtpconnect.org.au/Attachment?Action=Download&Attachment_id=54>.

Local manufacturing

Nine companies included in the analysis manufacture pharmaceutical products in Australia. These companies contribute to a larger proportion of employment value, with half of the estimated total direct jobs coming from companies that conduct local manufacturing.

Local manufacturing also creates increased imports and exports for Australia. For example, some of the survey respondents export a considerable amount of locally produced pharmaceutical products. There was an estimated $1.2 billion in exports for the five survey respondents that conduct local manufacturing. Results from the 2014 Australian Pharmaceuticals Industry Data Card showed estimates of almost $4 billion worth of exports for the total Australian pharmaceutical industry.[8]



Manufacturing supports local jobs and businesses, ensures surety of local supply and contributes to Australia's manufactured exports trade.

Table 3: Top five export countries by value (n=20)

Country	Export volume	Total value ($AUD)	Rank by value
China	11,635,000	476,651,050	1
Japan	460,650	119,190,390	2
Turkey	-	90,525,290	3
New Zealand	2,587,090	56,530,330	4
Korea	-	39,105,290	5

Source: Survey data, PwC Analysis

[8] Department of Industry and Innovation, 2014. 'Australian Pharmaceuticals Industry Data Card 2014', Commonwealth of Australia. Available from <https://industry.gov.au/industry/IndustrySectors/PharmaceuticalsandHealthTechnologies/Pharmaceuticals/Pages/PharmaceuticalsIndustryDataCard.aspx>.

Support of local businesses and organisations

Australian businesses which provide services and products to pharmaceutical companies benefit from the ongoing operations of the industry. There were approximately 18,600 business relationships between 18 industry survey respondents and Australian businesses at a value of almost $1 billion in 2016 (for 16 of the respondents). As a subset, 11 respondents reported business relationships with almost 2,250 small businesses worth almost $80 million.

Companies regularly hire local expertise to conduct business (e.g. medical experts). Sixty per cent of respondents that hire local expertise each year, do so at least on a monthly basis. A subset of 14 respondents estimated the expertise service costs to be $16.6 million for 2016.

Collaborations

Eighteen respondents stated that they have collaborations or strategic partnerships in Australia, and invested over $99 million (for 12 of the respondents) in these collaborations in the last full reported financial year.

A total of approximately **$99 million** was invested into collaborations and strategic partnerships across 12 respondents in 2016

The most common collaborations and partnerships took place with universities (67 per cent, or 10 of 15 respondents).

Almost half of respondents teamed up with other research bodies (47 per cent, or 7 of 15 respondents), hospitals or healthcare providers (40 per cent, or 6 of 15 respondents). Partnering with other pharmaceutical companies in Australia was also common for approximately half of companies responding to the survey (53 per cent, or 8 of 15 respondents).

Compassionate access

The majority (80 per cent) of the respondents provided compassionate access of some kind to patients in the last year. Compassionate access schemes have various names in the market including managed, facilitated or early access programs. These schemes are special arrangements that provide patients free or discounted access to drugs that are not PBS listed and/or TGA registered. In some cases compassionate access programs provide patients with a last resort option that they would not otherwise be able to access or afford.

The majority of respondents provided compassionate access in 2016

It became clear through the MA member interviews that compassionate access is a complex topic and schemes vary considerably across the market.

Respondents noted that their companies invest considerably through free or subsidised products and company resources to support supply and consider their compassionate access schemes an obligation to patients. Some noted that there risks to providing compassionate access. For example, some patients may need a drug for life, resulting in a long term commitment for the company.

The business environment over the last two years and the forward outlook

To better understand how the innovative medicines landscape has evolved over the past two years, a number of members were interviewed to comment on their experience. In addition, there were some relevant business environment questions in the survey. Key themes and responses are summarised below.

The last two years

Overall the last two years were considered challenging by interviewed companies. Almost all of the respondents have been impacted by pricing reforms in the last two years. In addition to price impacts, some companies had to manage the loss of exclusivity for major products.

The majority (70 per cent) of 23 respondents are also experiencing intellectual property challenges. Some of these challenges include patent related issues, data exclusivity and products being exposed to generic competition before patent expiry.

Future Challenges

Many companies are anticipating some usual challenges to continue into the future such as ongoing pricing pressure. They are also anticipating some new challenges such as growing patient expectations. The following section summarises some of the challenges identified in survey responses and interviews:

Processes to reimbursement

Companies noted the process to reimbursement could be more streamlined. The process is seen as inflexible and 'one size fits all'. In addition, the need for an approach to prioritise submissions for the most important new medicines (like the TGA priority review pathway) was noted by survey participants. There is also concern that the Government will have difficulty processing future submissions in a timely way with the more rapid innovation and a higher number of new submissions for reimbursement expected in the future. Vaccine providers noted that the current cost effectiveness criteria and reimbursement processes for assessing vaccines are not suitable and that vaccines should be assessed differently.

There is optimism that under the new Strategic Agreement, MA and the Government can work together to improve the process to PBS listing for the benefit of all stakeholders.

Price pressure for new medicines

Pricing pressure remains a significant concern for the industry. There is the perception that innovation through the pharmaceutical industry is not as valued as other health innovations or major infrastructure investments and that the benefits of new medicines are being undervalued in order to limit PBS spending.

The PBS budget for innovative medicine manufacturers is seen as a relatively easy target to achieve cost savings. The Department of Health is in the difficult position of having to find offsets for each new PBS listed drug and this is not considered a sustainable approach. Many companies have confidential rebate agreements with the Government and so additional discounts that the industry are making to support the sustainability of the PBS are not publicly available. Companies are concerned there won't be sufficient future budget to fund new medicines that are highly effective or curative, but may be more costly.

Sustainability of the health system

There are concerns that the overall health system is not sustainable with costs growing yearly and expected to increase in the future with the ageing population and chronic disease trends. It is assumed that the additional pressure on the system will lead to further pricing pressure for new medicines.

Respondents consider it unfair that there is considerable inefficiency in the overall health system, whilst the PBS budget is not growing at the same rate as overall health spending and cost effectiveness principles are not applied as rigorously to the rest of health spending as they are the for life sciences industries.

Many respondents mentioned that there needs to be an open debate around the future of the system, what is valuable to patients and society and what a reasonable cost to Government is. To remain in a universal health system in the future, many noted that the political and budget environment is challenging with siloes in the system required to be overcome and stakeholders need to come together to agree a common ground.

Intellectual property

There are ongoing concerns that intellectual property (IP) rights will be diminished, particularly after the Australian Government's Productivity Commission report released in December 2016 recommended patent reform for the pharmaceutical industry.[9] Local IP is a critical factor for global investment considerations and a strong and stable IP system is considered important to support local innovation and the supply of new medicines to Australians.

Patient expectations

Patient's expectations of the health system will continue to grow and they won't necessarily understand the principles of HTA and why medicines are available in other countries before Australia. The fast track approaches may not be enough to address future public demands around this.

[9] Productivity Commission, 2016. 'Intellectual Property Arrangements – Productivity Commission Inquiry Report Overview & Recommendations', Commonwealth of Australia. Available from <http://www.pc.gov.au/inquiries/completed/intellectual-property/report/intellectual-property-overview.pdf>.

With personalisation, patients may have different expectations of value which will be a challenge for the whole system including the pharmaceutical industry. Pharmaceutical companies need to plan for better consumer engagement which will be difficult given the existing limitations around engaging directly with consumers.

Medicines for rare diseases

Patients with rare diseases have limited treatment options, a challenge that is not straight-forward but needs to be addressed. The small patient population sizes for rare diseases makes it is difficult to conduct clinical trials, develop sufficient evidence for HTA and support PBS listing.
In addition, the small patient population sizes mean that it is challenging to get sufficient reimbursement to cover research and development costs, limiting the incentive for industry investment.

A few respondents noted that given the challenges, rare diseases should be managed differently through the HTA process, to improve the potential for treatment options for people with rare diseases. Others mentioned that incentives such as speed to market, IP and higher incremental cost-effectiveness ratio (ICER) thresholds for rare disease medicines could help to drive solutions from the industry perspective.

The future outlook

Based on interview conversations and survey responses, there is an overarching positive shift in the business environment for the pharmaceutical industry. For the future, there are a number of areas that are expected to be positive opportunities for the industry.

Expecting growth through new innovation

While the Australian reimbursement system remains a constraint, many companies have promising new medicines in the pipeline and are hoping these will be introduced in Australia. Twenty respondents are planning to bring a total of more than 50 new products to Australia in the next three years for PBS listing.

The Strategic Agreement with the Commonwealth

In 2017, Medicines Australia entered into a five year Strategic Agreement with the Commonwealth (on behalf of the innovative medicines industry) to support the sustainability of the PBS. As part of the Agreement, the industry will provide an additional $1.8 billion in PBS savings over the five year term and in return, the industry will have a period of stability and policy certainty that will give companies the confidence to invest in and bring new medicines to Australians. In addition, savings from the agreement will be set aside to fund future PBS listing of innovative medicines. The Government has also committed to process improvements including a 50 per cent reduction in pharmaceutical company submission churn for PBAC approval to list a medicine on the PBS

Overall, the MA members interviewed perceive the Strategic Agreement to be a positive development. Although the price cuts are not viewed favourably, they are considered a necessary trade-off to make room for new products and provide a level of certainty for the next five years which can allow companies to better plan for the future. The commitment to reinvest savings back into health was viewed as more fair and a very positive outcome from the agreement.

Improvements to the clinical trials environment

The focus on innovation through the NISA is considered a positive outcome for local research and Australia's competitive stance to attract local clinical trials, as well as Australian pharmaceutical manufacturing and R&D. The establishment of MTPConnect is considered positive and provides industry with opportunities to build strong relationships with Australian researchers.

Participants noted a greater appreciation by Government and stakeholders for the value of innovation from the pharmaceutical industry however companies mentioned that more can be done to support local clinical trials. Fourteen survey respondents claimed the R&D tax incentive in 2016.

Potential to attract more local manufacturing and R&D

Australia is seen as a high potential location for future investment if the business environment could be made more promising with policies to support local manufacturing and research. Considerations include improvements in intellectual property standards to comparable international standards, tax incentives, immigration policy to support research and valuing innovation in price negotiations for PBS listing.

Companies mentioned that these considerations would be important for future potential growth of local manufacturing and research but to also maintain the current levels of investment in these areas with the ever increasing global competitiveness.

TGA reforms

The TGA is implementing a priority review pathway that will provide a faster assessment of vital and life-saving prescription medicines. The timeframes could mean registration of important medicines three months earlier than the standard process. The approach to prioritise and 'fast track' the most important new medicines for society are considered to be a potential area for improvement for the reimbursement processes as well.

Abbreviations and terms

FTE	Full-time equivalent for employment
Gross Value Added (GVA)	A measure of the industry production value and the contribution to overall gross product and is considered a good estimate of economic contribution because it removes distortion caused by taxes and subsidies across different industries
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratio
Innovative pharmaceutical industry	Discovery driven companies, not including companies that solely provide generic pharmaceutical and vaccines
IP	Intellectual Property
MA	Medicines Australia
multiplier	Used to quantify economic impacts or changes in economic activity resulting from a stimulus
non-MA	Innovative pharmaceutical companies who are not a member of Medicines Australia
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	The Pharmaceutical Benefits Scheme
Respondent	Company that responded to the specific question in the survey
R&D	Research and Development
TGA	Therapeutic Goods Administration