



**Submission to the 2016-17  
Federal Government Budget**

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## Executive Summary

Medicines Australia welcomes the opportunity to contribute to the 2016 Federal Budget process. Medicines Australia is the peak organisation representing the research-based pharmaceutical industry in Australia. Our members comprise over 86% of the prescription medicines market by value and play an integral role in keeping Australians healthy and able to participate and be productive.

The pharmaceutical industry has a valuable contribution to make to Government's social, economic and reform agenda. This submission will demonstrate how Government could recognise and incorporate the economic and societal value from the investments and innovations made by the pharmaceutical industry into policies that will benefit consumers, taxpayers and the wider community. Further, the submission provides case studies of industry investment and value.

By delivering a stable and predictable PBS policy environment, the Government will help to maintain universal access to medicines, and encourage manufacturers to undertake long-term innovative medicines research and development in Australia to further enhance prevention, treatment and cure of illness and disease. This can be achieved through recognising and measuring the long term benefits of listing medicines on the PBS; in terms of life years saved, improved productivity and the savings provided outside of the PBS. Nevertheless, we recognise the challenging fiscal environment and the hard choices that Government must make in pursuing its policy goals.

Cognisant of this, Medicines Australia makes the following recommendations for Government's consideration for inclusion in the 2016-17 budget:

## Recommendations

**Recommendation 1:** Consider listing new innovative and cost-effective medicines without the need to find direct cost-offsets.

**Recommendation 2:** Consider investing the total aggregated value of industry rebates from sponsors directly back into PBS.

**Recommendation 3:** In accordance with the National Medicines Policy, commit to PBS policy stability and predictability given significant recent reform in the sector, to support a responsible and viable industry sector.

Medicines Australia notes that the 2015-16 Budget resulted in regrettable outcomes both for the pharmaceutical industry and, in our view, for Australian innovation and health. Appendix A provides an overview of these outcomes together with the ongoing implications for the industry from these measures.

Despite the challenging environment, Medicines Australia continues to welcome the Government's stated commitment to timely access to new medicines and innovation. Medicines Australia continues to support policies such as seeking Cabinet consideration of listing new PBS recommended drugs (including vaccines) within 6 months of the PBAC recommendation. With the announcement of the Government's National Innovation and Science agenda Medicines Australia would also welcome the opportunity to further discuss how these measures could be implemented to benefit patients through greater access to life saving medicines.

## **Introduction**

Australians value access to medicines through the Pharmaceutical Benefits Scheme (PBS) and vaccines via the National Immunisation Programme. 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 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.

The Australian pharmaceutical industry requires predictability and stability in policy settings, along with timely reimbursement for the medicines and vaccines it brings to patients and consumers, to provide ongoing investment in Australia's health sector and the wider economy. The innovative pharmaceutical industry is not just a critical pillar of the health sector, but also a key creator of highly skilled jobs that contributes to broader productivity in the Australian economy.

## **The Industry and the wider economic and societal value from pharmaceutical investments and innovations**

### **The pharmaceutical industry drives Australian innovation**

The pharmaceutical industry is a highly innovative and knowledge-intensive sector which creates thousands of high value jobs for Australians. The industry makes a substantial contribution to economic productivity and economic growth by:

- investing approximately \$1 billion in R&D each year
- employing over 13,000 Australians and supporting an eco-system of smaller Australian businesses
- exporting up to \$4 billion worth of goods and services to over 30 countries around the world.<sup>1</sup>

The innovative pharmaceutical industry welcomes the announcement of the Government's National Innovation and Science agenda (NISA). As outlined below, the industry is already an important contributor to the development and commercialisation of Australian biomedical innovation and values the opportunity to contribute further through the new agenda.

### **Contributions to commercialising Australian research**

As an industry that derives reward through innovation, the pharmaceutical sector is one of Australia's biggest investors in research and development. Since 2005-06, this investment has grown by more than 60 per cent, accounting for 9 per cent of all business expenditure on research and development in Australia in 2011-12.<sup>2</sup>

Many of Medicines Australia member companies have made critical contributions to the commercialisation of Australian innovation. This has led to breakthroughs such as GARDASIL, the

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<sup>1</sup> Medicines Australia Factsbooks 4th Edition

<sup>2</sup> Department of Industry, Canberra, 2014, Australian Pharmaceuticals Industry Data Card 2014.

first cancer vaccine, which was developed from Australian technology in collaboration with member companies of Medicines Australia. Similar collaborations are announced regularly and are critical to Australia realising the benefits of the ideas-boom in biomedical research. Two recent case studies follow below:

**CASE STUDY 1: Boehringer Ingelheim and Pharmaxis**

Boehringer Ingelheim and the Australian pharmaceutical company Pharmaxis announced in May 2015 that Boehringer Ingelheim acquired the investigational drug PXS4728A, to develop it for the treatment of the liver-related condition NASH. NASH is the progressive form of non-alcoholic fatty liver disease (NAFLD), the most common liver disorder in developed countries. It is regarded as a major cause of fibrosis and cirrhosis of the liver and is an area of high unmet clinical need. The high prevalence of type 2 diabetes and obesity, which can lead to NASH and its long term consequences, is considered to make NASH one of the most common causes of advanced liver disorders in coming decades. The potential value to Pharmaxis is in excess of \$A750 million which will help it develop other innovative medicines.

**CASE STUDY 2: MSD and Bionomics**

Also this year, MSD announced a \$12.5m investment in the Adelaide based Bionomics for the discovery and development of drug candidates for the treatment of chronic and neuropathic pain. This investment builds on a collaboration agreement concluded in 2013, also related to pain therapy worth US\$172m and an agreement on cognitive impairment research worth up to US\$506m. In announcing the agreement, Dr Iain Dukes Senior VP, Business Development & Licensing Merck Research Laboratories noted that “establishing strong long-term external collaborations is central to our business development strategy”.

Many pharmaceutical companies have similarly partnered with independent medical research institutes, recognising them as major sources of health innovation for medicines and vaccines in Australia. These collaborations provide students with the opportunity to utilise state of the art facilities and develop their real-world skills, while industry benefits from a competitive edge with access to world class researchers and facilities to enable innovative industrialisation capability. Critically, the development of this infrastructure and capability nurtures new biotech companies in Australia and creates highly skilled jobs.

Medicines Australia welcomes the additional measures identified in the NISA together with previous budget measures including the Medical Research Future Fund. In particular, the creation of the Biomedical Translation Fund is a critical step forward in improving the commercialisation of Australian biomedical research. As outlined in the case studies above, innovative pharmaceutical companies are actively involved in collaborating with universities and research organisations, and concluding collaborative deals to commercialise promising therapeutic candidates. The capital, collaborative and skills based initiatives in NISA will all facilitate and accelerate the commercialisation of Australian research.

The innovative medicines industry further commends NISA for its recognition of Government's pivotal role in encouraging and supporting innovation (i.e. "government as exemplar"). Australia's early adoption of health technology assessment through the PBS helped to focus the research priorities of innovative medicines companies on therapies that delivered the greatest incremental benefit. However, more recent policy changes, including policies in the PBS Access and Sustainability Package, have imposed arbitrary cuts on sunk investments, which undermine the confidence needed to support long-term investments in biomedical innovation. Medicines Australia would welcome the opportunity to discuss how to ensure that all its policies are consistent with its intent to pursue innovation-driven economic growth.

### **Contributions to high-value Australian manufacturing**

Like many other industries, Australian pharmaceutical manufacturing has struggled to compete globally, particularly at the lower value end of the market. Comparable jurisdictions have seen much stronger growth over recent years<sup>3</sup>.

#### **CASE STUDY 3: AstraZeneca Investment in Infrastructure**

AstraZeneca (AZ) currently exports to 30 countries across all parts of the world. Since 2010 their export growth has risen from \$310m to \$511m in 2015 and is projected to increase to \$2b by 2025. In 2016, 81% of export volume is destined for China with 445m units of respules, treating over 10m patients with respiratory illness.

Since 2010, the headcount at the Sydney manufacturing site increased by 100 to 431 in 2015 and will further increase to 700 by 2023. The site operates 24 hours a day, 7 days per week to meet demand. Apart from highly trained production staff and engineers AstraZeneca also has an outstanding quality assurance team that are at the cutting edge of testing and validating quality to ensure the highest standards are maintained for medicines destined for export and the local market.

AstraZeneca also create a significant impact on the local economy. In 2015 they have supported local businesses who provide a variety of services, packaging materials and consumables (\$25m) to meet the needs of growing volume and people on site. An AZ commissioned report estimated that for every dollar of export value AZ contributes an additional 20 cents to the many Australian owned businesses that support their manufacturing operations. Finally, AZ have a strategic partnership with Andrew Donald Design Engineering (ADDE), a Melbourne base industrial automation manufacturer that has custom built machines that operate round the clock, to produce medicines intended for patients with respiratory illness in China.

\$90m has been invested to date to support export growth, automate processes and invest in technology; which includes 6 packing lines. A further \$100m will be invested to expand to 10 packing lines by 2023. Of this investment nearly 60% is spent locally. Machines to support the production lines are custom-built by ADDE ensuring that our Australian investment dollars flow into an

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<sup>3</sup>International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), The Pharmaceutical Industry and Global Health Facts and Figures 2012 at page 49. Accessed online 29 July 2014: [http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA - Facts And Figures 2012 LowResSinglePage.pdf](http://www.ifpma.org/fileadmin/content/Publication/2013/IFPMA_-_Facts_And_Figures_2012_LowResSinglePage.pdf)

Australian owned engineering firm. If this level of growth continues beyond 2023 there are options to invest in further expanding the manufacturing plant at North Ryde.

There are 33 professionals plus local consulting companies employed each year on capital projects to deliver packing lines on time, on budget, as well as upgrade technology and infrastructure to support the growth on site.

Nonetheless, there are positive examples of where industry has been able to achieve growth in manufacturing through innovation supported by the Government. Medicines Australia would welcome an opportunity to discuss how the NISA could be further supported through the budget process in fostering a more competitive manufacturing environment for innovative pharmaceutical companies.

#### **CASE STUDY 4: GSK Blow-Fill-Seal**

GSK recently transformed their Victorian manufacturing facility to shift away from traditional manufacturing such as tablet packaging in order to focus and invest in hi tech 'Blow-Fill-Seal' technology and increase export volumes. The new vaccines pilot manufacturing facility, an outcome of collaboration with Monash University, was awarded a Federal Grant as part of the Manufacturing Transition Programme earlier this year. The vaccines project which this grant support is an example of a critical opportunity for industry in Australia to develop new capabilities in advanced manufacturing and vaccines.

### **Contributions to Australian clinical trials**

In Australia, clinical trials support thousands of high paying technical jobs. These jobs are vital in improving the health and wellbeing of Australians, with over 900 new clinical trials conducted in 2014<sup>4</sup>. However, Australia has become one of the most expensive locations for clinical trials in the world and is facing increasing competition from countries with larger patient populations, increasingly advanced health care systems, and lower operational costs.<sup>5,6</sup>

While the Government should be applauded for continuing the Health Industry Forum and for focusing on improving the clinical trial environment, key emerging clinical research locations in Asia, Eastern Europe and South America are still providing Australia a significant challenge in attracting and retaining the best clinical trials.

Government leadership is required to maintain the viability of Australia within the clinical trial sector and reduce red tape. Medicines Australia strongly supports the recent reform measures implemented by the Government across the NHMRC, Department of Industry, Innovation and Science and Department of Health. Further urgent and positive action is still needed to ensure

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<sup>4</sup> Therapeutic Goods Administration 2015. Half Yearly performance reports. Available: <http://www.tga.gov.au/publication/half-yearly-performance-report-january-june-2015>

<sup>5</sup> <http://www.idaireland.com/business-in-ireland/research-development-and-/incentives-in-rdi/>

<sup>6</sup> Medicines Australia, Keeping clinical trials in Australia: why action is needed now (MA Occasional Paper Series, Paper 3), Canberra, 2011, p. 7, available at <http://medicinesaustralia.com.au/issues-information/publications/occasional-papers/>

Australia remains an attractive destination for clinical trial investment. A few ongoing challenges include:

- a slow and inefficient regulatory processes for approval for multi-centre clinical trials;
- non-existent or inadequate patient referral networks that would enable faster patient recruitment and therefore trial completion; and
- extremely high and unpredictable cost of conducting clinical research in Australia.

The solutions have been identified through the 11 recommendations of the Clinical Trials Action Group<sup>7</sup> and whilst industry recognises that implementing national reforms can and has been complex and time-consuming, the pace of implementation could be enhanced.

### **The importance of a supportive tax regime**

The innovative pharmaceutical industry has long been advocating for a supportive and globally competitive tax regime. In an ever increasingly multinational investment environment, it is important now more than ever to ensure that corporate tax rates are internationally competitive with other regional jurisdictions.

A positive example of more recent tax policy that has supported innovative investment is the current R&D Tax Incentive system. This new system replaced one that was unpredictable, overly complicated and required companies in Australia to demonstrate year-on-year growth in their R&D expenditure in order to secure a tax benefit. Cutting the rate or otherwise restricting the eligibility criteria beyond what has already been done would mean that other countries, which offer more generous tax incentives, would attract an even greater share of global R&D investment than they do now, at Australia's expense. Improvements to the tax incentive programme could include a period of corporate tax exemption or lower corporate tax rate in return for certain thresholds of manufacturing investment.

### **Intellectual Property (IP)**

The strengthening of Australia's IP system to better support investment in new breakthrough medicines will lead to better health for Australians. With supportive policy settings the pharmaceutical industry has the potential to be one of the key innovative industries for Australia's future, as identified by the Government through the NISA and Industry Competitiveness Agenda<sup>8</sup>.

Continued innovation is fundamental to Australia's economic well-being and industries which rely on IP play a key role in driving economic growth, jobs, and competitiveness. As the 2015 Intergenerational Report noted, Australia is poised for growth through "harnessing future opportunities to support innovation, adopt new technologies, facilitate foreign trade and investment and foster competition [which] can boost future productivity growth and living standards." Strong intellectual property systems foster an innovative culture and provide incentives for increases in technology transfer, foreign direct investment and local R&D capacity. Such a system will help:

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<sup>7</sup> Clinical Trials Action Group 2011. <http://hrep.nhmrc.gov.au/ctag>

<sup>8</sup> Australian Government 2014. Industry Innovation and Competitiveness Agenda



- increase the return on inventions and developments made possible by the significant level of public support for medical research in Australia,
- provide greater incentive and certainty for the commercialisation of local, Australian health technology inventions and developments – supporting Australia’s rapidly developing biotechnology sector,
- attract additional global investment in Australia’s research and development efforts, and
- increase access to new medicines and vaccines for Australian patients (including early access via increased clinical trial activity).

Harmonisation across IP systems and making sure Australia’s system meets international standards is a critical role for Government. Continuing work to bring our IP system in line with other leading OECD countries will improve Australia’s attractiveness as a destination for foreign investment by global Pharmaceutical companies. Medicines Australia calls on the Government to reflect further on how strengthening IP in Australia will help support innovation and growth in the innovative pharmaceutical sector. Without a strong IP system, innovative pharmaceutical companies will have a reduced incentive to invest in new medicines, delaying access that would improve Australians’ health.

## **The value of medical innovation**

The innovative pharmaceutical industry has been providing a number of broader benefits to Government and the Australian economy for over the past 50 years. Opportunities currently exist for Government to incorporate the long term benefits of listing of medicines on the PBS in terms of life years saved, improved productivity and the savings provided outside of the PBS into the Budget.

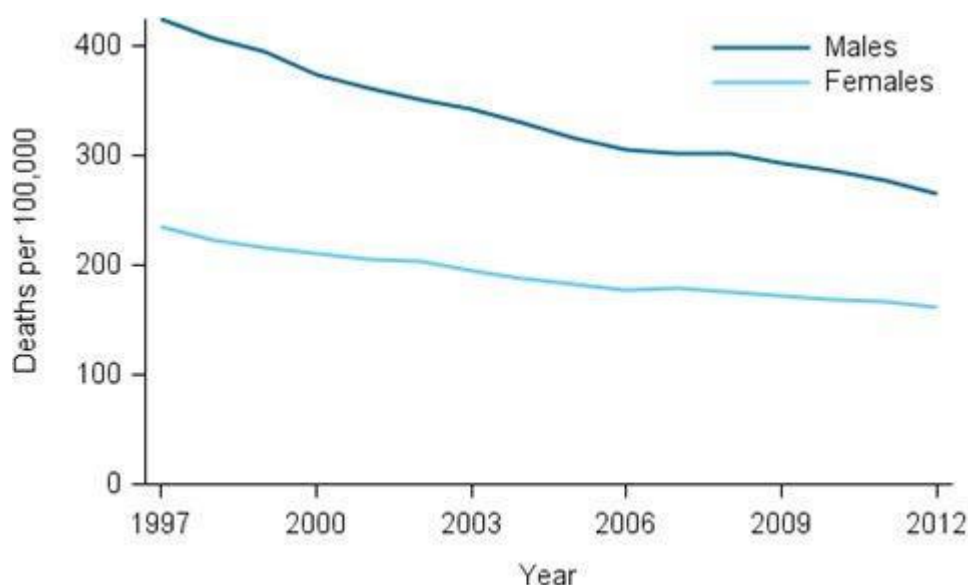
### **Lifesaving medicines deliver great value to Australian patients**

The best access to medicines exists when the foundations focus on rewarding innovation and encouraging future investment. Access to innovative pharmaceutical (including vaccines) products over the past fifty years has had a profound impact on the wellbeing and health of Australian patients. This impact has increased dramatically in recent years, with access to pharmaceuticals being one of the major contributors. The Australian Institute of Health and Welfare estimates that the number of premature deaths before the age of 75 fell by over a third between 1997 and 2012<sup>9</sup> (Figure 1).

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<sup>9</sup>The Australian Institute of Health and Welfare. Trends in premature mortality. <http://www.aihw.gov.au/deaths/premature-mortality/trends/> Accessed 1/12/15

**Figure 1: Age-standardised death rates among people aged less than 75, by sex, 1997–2012<sup>1</sup>**



Recent research by Lichtenberg (2015) of Colombia University attributes 60% of the decline in premature mortality in Australia over this period to the listing of innovative medicines on the Pharmaceutical Benefits Scheme (PBS)<sup>10</sup>. The value of innovative medicines is further illustrated by observing the changes in mortality in patients with diseases where there have been significant advances in treatment. For example, deaths from heart disease and other circulatory diseases has fallen more than five-fold since the late 1960s<sup>11</sup> and deaths from AIDS from 764 in 1994<sup>12</sup> to 75 in 2013.

Cancer survival has also improved substantially in recent years, with 5 year cancer survival increasing from 49% in 1986 to 62% in 2007. Lichtenberg (2015) estimated that innovative medicines contributed 40% of this survival gain. These improvements in health and wellbeing from innovative pharmaceuticals is likely to lead to other societal benefits as well, through reduced productivity loss, higher participation rates, reduced burden on the hospital system and greater social connectedness.

In addition to saving lives, investments in the PBS also have important benefits for other parts of the health system as well. In the absence of the PBS listing of new innovative medicines, Lichtenberg (2015) calculated that there would have been more than a million extra hospitalisations in 2011, costing \$7 billion, significantly more than the \$5 billion that Government would have spent on innovative medicines on the PBS.

<sup>10</sup> Lichtenberg, F. 2015. The Impact of Pharmaceutical Innovation on premature mortality, hospital separations and cancer survival in Australia. <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20151124-Lichtenberg-paper.pdf>

<sup>11</sup> The Australian Institute of Health and Welfare. Trends in deaths. <http://www.aihw.gov.au/deaths/trends-in-deaths/#cause> Accessed 16/12/15

<sup>12</sup> Australian Bureau of Statistics. Mortality & Morbidity: Acquired immunodeficiency syndrome. <http://www.abs.gov.au/ausstats/abs@.nsf/2f762f95845417aeca25706c00834efa/455cdc7e9de1185fca2570ec001b1378!OpenDocument> Accessed 16/12/15

The analysis above shows the value of innovative medicines, both to the Australian public and to the health system more broadly. Investment in the PBS not only saves lives, it also averts future hospital spending, improves productivity and improves the quality of life of patients, their families and their communities. Australians rightly regard the PBS as a cherished part of their health system.

As highlighted by the first two case studies, the biosciences industry is on the cusp of major breakthroughs in important disease areas, including cancer, infections and Alzheimer's. While the absolute cost of these medicines will be high, this is more than offset by the value they deliver to patients, Government and taxpayers through the time, effort and substantial investment risk needed to discover and test them.

The policies that the Government chooses to pursue through the PBS should be framed with regard not only for what innovative medicines themselves deliver, but also for their impact on the long term innovation system that delivers new medicines for currently incurable diseases in the future.

## Continued sustainability of the PBS

**Recommendation 1:** Consider listing new innovative and cost-effective medicines without the need to find direct cost-offsets.

Medicines Australia believes that it is important that the Commonwealth view expenditure on medicines, through the PBS, as an important investment to improve the future health, well-being and economic prosperity of Australians whilst contributing productivity benefits.

Medicines Australia acknowledges the current fiscal challenges that face Government. However, Medicines Australia strongly believes that patient access to new medicines via the PBS should not be delayed once a listing recommendation has been made by the PBAC. The Government spends an estimated \$154.6 billion per year, or 9.8% of GDP, on health (2013-14)<sup>13</sup>. Around 42% of total health expenditure is funded by the Commonwealth, around 27% is funded by the states and territories, and the rest is funded by patients including via private health insurance and personal contributions<sup>14</sup>.

Medicines Australia acknowledges that offset savings measures are taken within the health portfolio to allow for expenditure on new PBS listings. This was first introduced around the time of the global financial crisis by the Government given the structural state of the budget and the objective of achieving a 'surplus'. This objective of finding spending offsets within the health budget to fund new medicines creates delays to the availability of new and innovative medicines that are of benefit to Australians. This also leads to a highly unpredictable business environment in Australia. Significantly delaying patient access to new and innovative medicines and creating uncertainty in the Australian business environment are at odds with the National Medicines Policy.

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<sup>13</sup> AIHW 2015. Health Expenditure Australia 2013-14. Available: <http://www.aihw.gov.au/publication-detail/?id=60129553112>

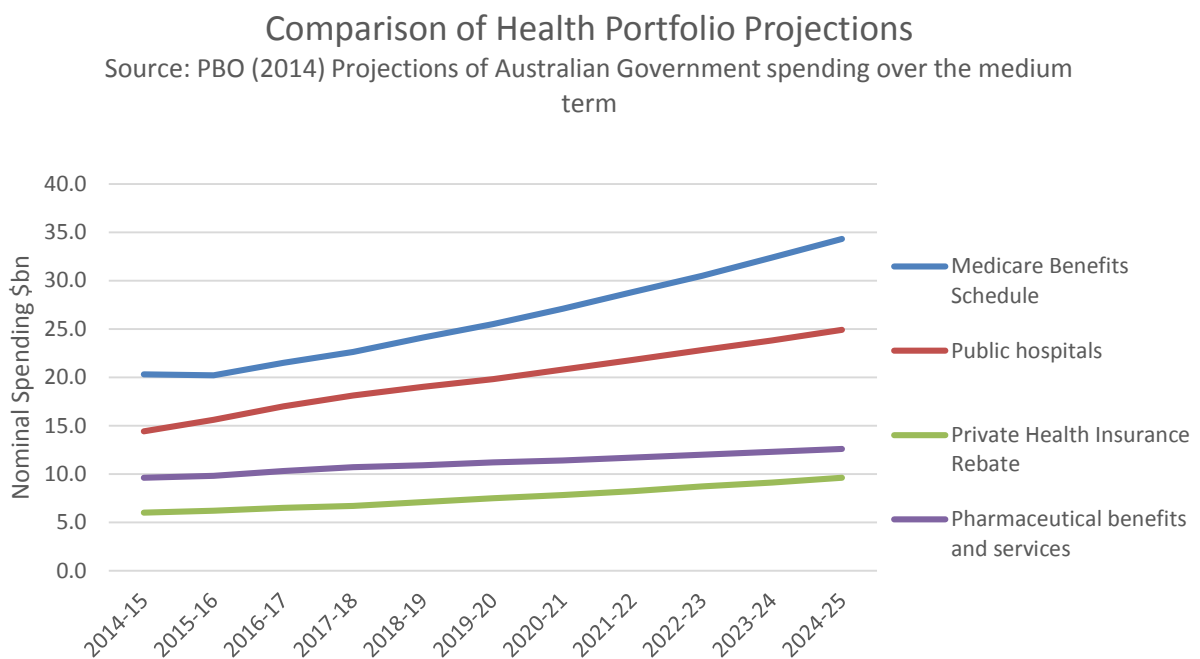
<sup>14</sup> Ibid.

To some within Government the current level of total expenditure on health is of concern as it has increased over time. However, health expenditure should not be seen in isolation. Any increase in health expenditure is intertwined with changes in Australian society such as the increased growth in incomes leading to greater demand from individuals for a range of health care services. Another driver has been an increase in the population most likely to use healthcare resources due to increasing prevalence of chronic diseases.

Over the 40 year period 1973 to 2013 the population aged over 65 years has tripled compared to a 22% increase in those aged 25 years and under. With an increasing older population it is likely that there is an increased prevalence of chronic conditions and risk factors. Minimising certain risk factors through lifestyle choices, and where required medicines, could reduce the prevalence of chronic conditions and reduce the incidence of associated costly hospitalisations.

Importantly, the growth in total health expenditure is primarily driven by the Medicare Benefits Schedule and public hospital spending, with the PBS forecasted to be one of the slowest growing in terms of expenditure (Figure 2).

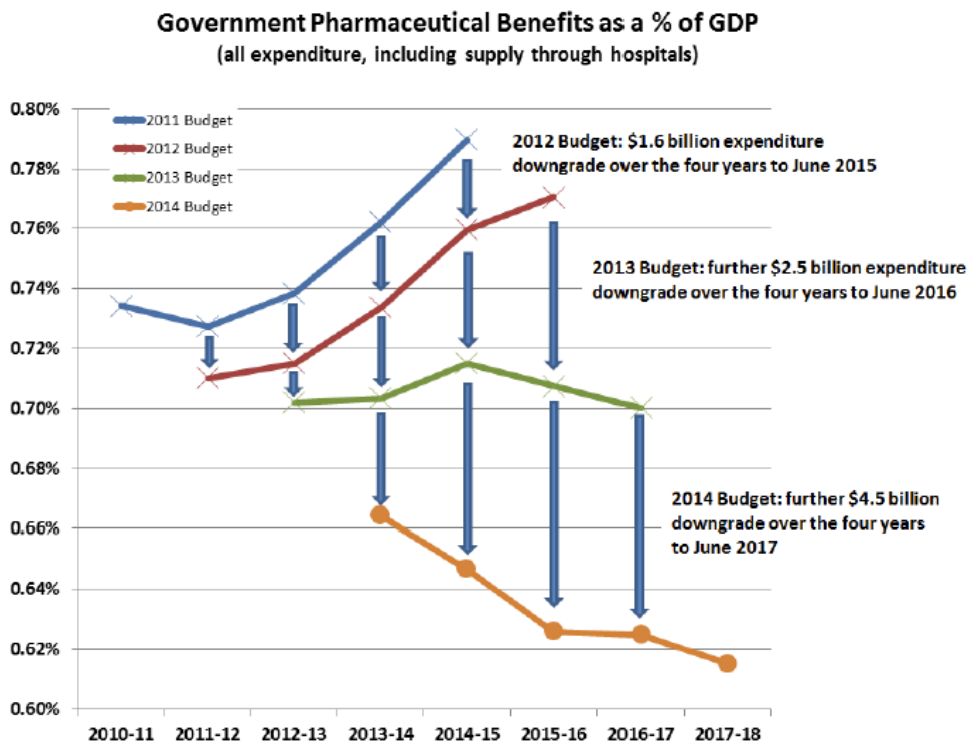
**Figure 2: Projections of health portfolio spending over time**



**Commonwealth spending on medicines as a proportion of GDP**

Many cost saving initiatives implemented by the Government have a delayed impact with PBS budgets continuing to be revised downwards due to the reduced spending on medicines from previous reforms. The Commonwealth spending on PBS medicines as a proportion of GDP is around 0.6%, and has fallen significantly over the past five years due to reform measures (Figure 3).

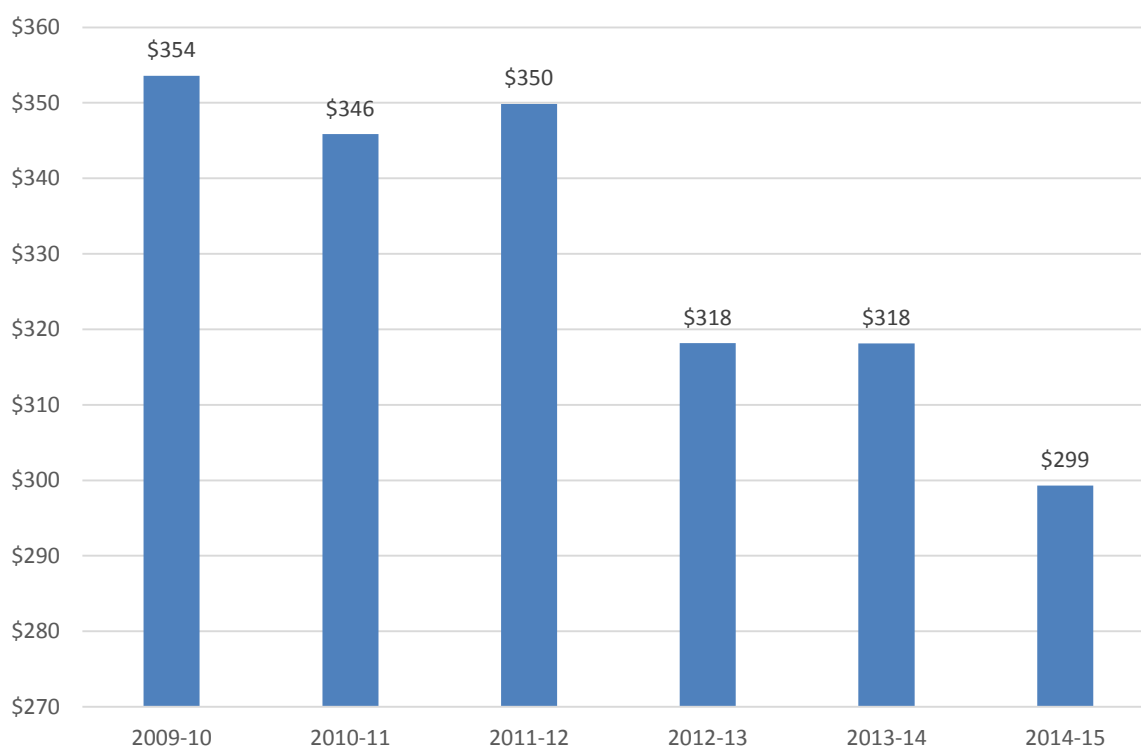
**Figure 3: Government spending on medicines as a proportion of GDP**



This continuing decline in Commonwealth spending on the PBS as a proportion of GDP reflects the current sustainability of the system and ongoing impact of previous reforms. The recent Productivity Commission Report on Government Services (2016)<sup>15</sup> reinforces the sustainability of the PBS, as shown by the decline in the cost of spending per person from \$354 in 2009-10 to \$299 in 2014-15 (Figure 4).

<sup>15</sup> Productivity Commission 2016. Report on Government Services – Volume E: Health. Available: <http://www.pc.gov.au/research/ongoing/report-on-government-services/2016/health/rogs-2016-volume-e-health.pdf>

**Figure 4: PBS Total Expenditure per Person<sup>16</sup>**



Importantly, any new medicines that have been through the rigorous approval processes of the TGA and PBAC are required by legislation to be found clinically effective and cost-effective. Therefore, every dollar spent on the PBS represents a justified investment in the health of the population. Medicines Australia believes that once these rigorous processes of the TGA and PBAC have been complete there should be no delays in making new medicines available to Australians. Medicines Australia would welcome an opportunity to work with the Government to achieve this.

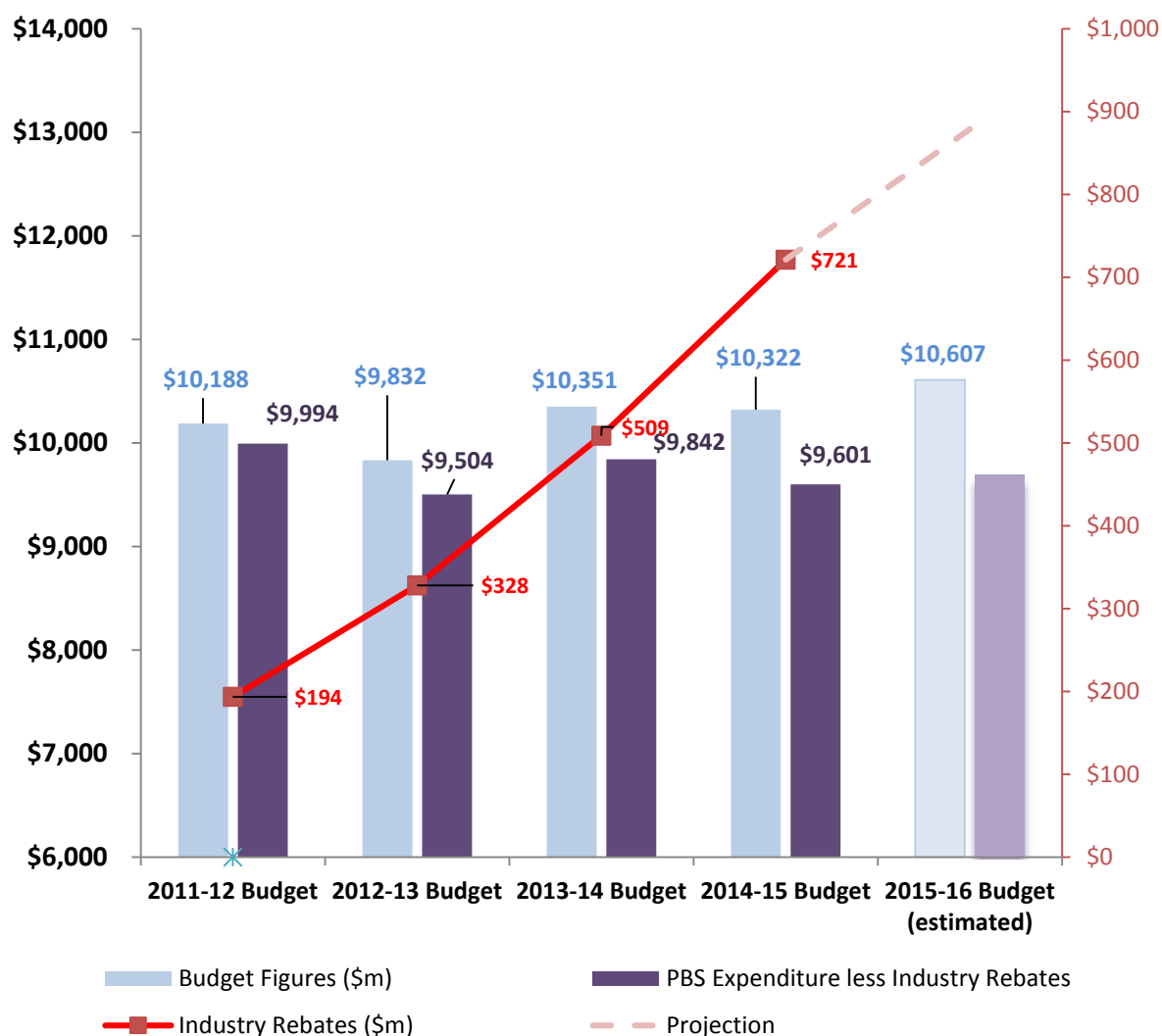
## Impact of Rebates

**Recommendation 2:** Consider investing the total aggregated value of industry rebates from sponsors directly back into PBS.

Medicines Australia member companies are contributing to maintain a sustainable PBS through rebates paid to the Government for high cost drugs. The Commonwealth's spending on PBS medicines is likely to be even lower if the rebates paid by industry are taken into account. These contributions by industry are not captured in projections and graphs of PBS growth. Over the past five years, the growth in rebate agreements between industry and Government has been growing whilst PBS growth has remained flat (Figure 5). This total rebate is not usually reported in the Budget papers and so the PBS expenditure could be reported in more detail to accurately inform Australians on the actual total net expenditure.

<sup>16</sup> Productivity Commission 2016. Report on Government Services – Volume E: Health. Available: <http://www.pc.gov.au/research/ongoing/report-on-government-services/2016/health/rogs-2016-volume-e-health.pdf>

**Figure 5: Expenditure on PBS and related services growth compared to industry rebates (\$m)**



Medicines Australia would welcome the opportunity to discuss how the total rebates figure received by the Commonwealth could be acknowledged in the Budget and reinvested in the PBS to fund new medicines.

### Impact of the recent measures introduced by the Commonwealth

**Recommendation 3:** In accordance with the National Medicines Policy, commit to PBS policy stability and predictability given significant recent reform in the sector, to support a responsible and viable industry sector.

The Commonwealth’s PBS Access and Sustainability Package announced in 2015 will deliver even more savings to the PBS, forecasted to be over \$3.7 billion net over the forward estimates. Many of the measures including the one-off 5% statutory price reduction for certain F1 medicines, the changes to price disclosure arrangements for medicines in the F2 formulary, and the flow-on price disclosure reductions to combination medicines will primarily impact Medicines Australia members. The intent of these and other measures is to “ensure ongoing access to innovative medicines

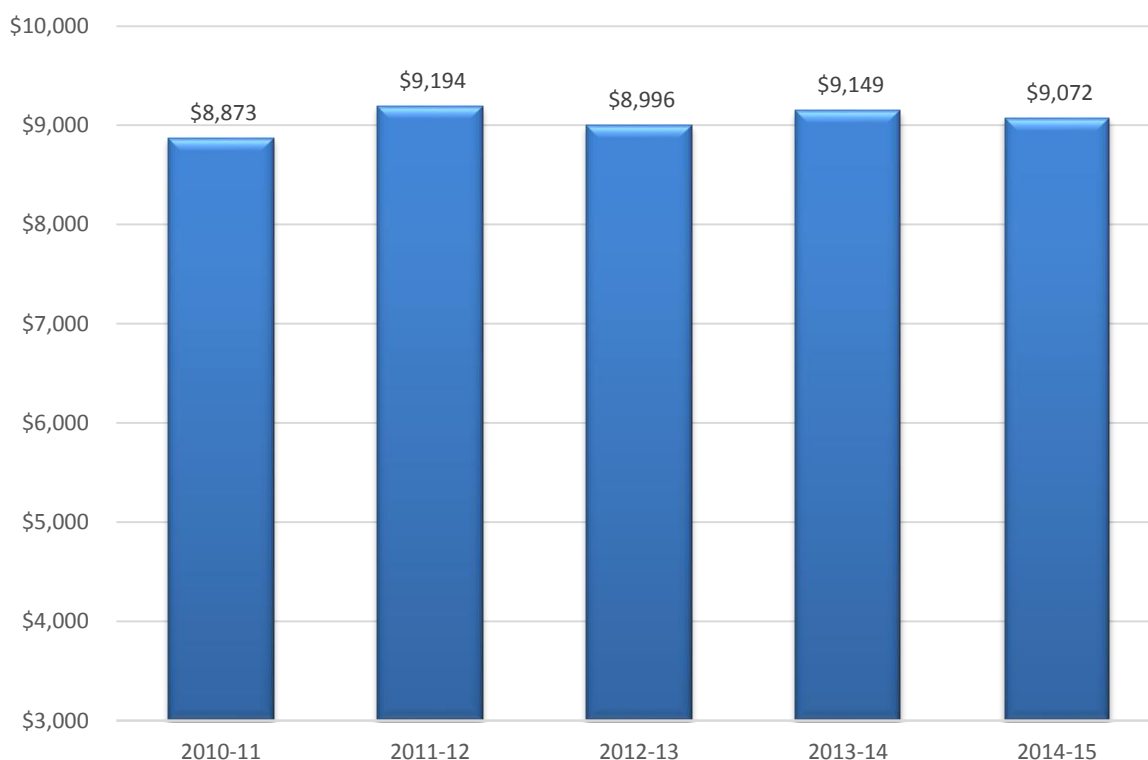
through a sustainable PBS".<sup>17</sup> The measures introduced as part of the package are outlined in Appendix A.

### The Ongoing Impact of Previous Reforms

Previous price disclosure reforms are having an ongoing substantial effect on PBS expenditure and the overall health budget. As price disclosure is embedded in legislation and applied on a cyclical basis to reflect ongoing market discounting and the arrival of new generic medicines, it will continue to deliver substantial savings into the future. Unlike most other areas of Government health expenditure, any new PBS listings are required by legislation to be found cost-effective by the independent Pharmaceutical Benefits Advisory Committee. As a result of this rigorous process, every dollar spent is a value dollar.

PBS reforms had begun to flow through by the time the 2015 Intergenerational report (IGR) was released, and with PBS growth flattening in recent years. Since 2010, PBS expenditure excluding payments to related services has been flat, and is well below inflation, with the five year growth being just 2.2% (Figure 6). This period of stability in expenditure further highlights the sustainability of the PBS.

**Figure 6: PBS Expenditure (Medicines component\*) \$m<sup>18</sup>**



*\* Includes payments to wholesalers, manufacturers and pharmacists, but excludes payments related to other services*

However, the full savings derived from ongoing price disclosure reforms were not yet fully apparent or factored in – whole classes of drugs are now experiencing massive cost reductions through their

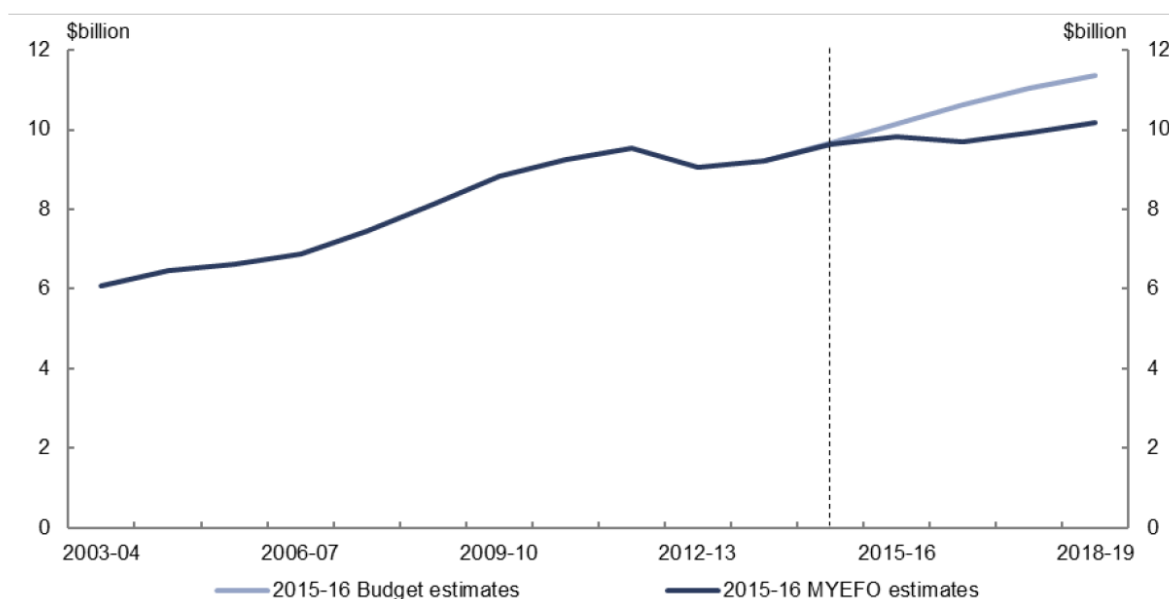
<sup>17</sup> National Health Amendment (Pharmaceutical Benefits) Bill 2015 explanatory memorandum.

<sup>18</sup> Department of Health and Ageing, multiple year annual and pharmaceutical expenditure reports. Available [www.health.gov.au](http://www.health.gov.au)



life cycle, as they have come off patent and are exposed to generic competition. As noted in the 2015 IGR, Government real pharmaceutical spending is projected to be one of the slowest growing components<sup>19</sup>. As shown through the 2015 Mid-Year Economic and Fiscal Outlook estimates of PBS expenditure, the rate of growth is expected to slow even further (Figure 7). The 2015 MYEFO update has revealed further higher than expected savings from existing pricing policies, with \$549m in reduced PBS payments from existing savings measures. This reduction is expected to be up to \$1.6 billion over 4 years to 2018-19<sup>20</sup>.

**Figure 7: PBO Pharmaceutical Benefits change from 2015-16 Budget to 2015-16 MYEFO estimates<sup>21</sup>**



It is against this backdrop of managed expenditure that Medicines Australia asserts that new PBS pricing reforms or other unilateral savings measures are unnecessary while price disclosure continues to exert such a strong influence on the sector and deliver ongoing savings.

Medicines Australia and its members require policy stability and a period where no new cost-saving measures are introduced. Sufficient time is required to allow time for the industry to adjust to the measures announced in the PBS Access and Sustainability Package. Medicines Australia remains concerned about the unintended consequences of these measures on the industry. Medicines Australia would also welcome the opportunity to work with the Government on the introduction of certain reforms such as the Biosimilars Awareness Initiative.

<sup>19</sup> Treasury 2015. 2015 Intergenerational Report Australia in 2055. Available: [http://www.treasury.gov.au/~media/Treasury/Publications%20and%20Media/Publications/2015/2015%20Intergenerational%20Report/Downloads/PDF/2015\\_IGR.ashx](http://www.treasury.gov.au/~media/Treasury/Publications%20and%20Media/Publications/2015/2015%20Intergenerational%20Report/Downloads/PDF/2015_IGR.ashx)

<sup>20</sup> Parliamentary Budget Office 2015-16 Mid-Year Economic and Fiscal Outlook – charts. Available: [http://www.aph.gov.au/About\\_Parliament/Parliamentary\\_Departments/Parliamentary\\_Budget\\_Office/Chart\\_packs](http://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Budget_Office/Chart_packs)

<sup>21</sup> Ibid.

## Conclusion

Medicines Australia remains committed to working with Government to ensure the sustainability of the PBS and this country's medicines industry over the long term whilst also ensuring that Australian patients benefit from receiving world class innovative therapies. Incorporating and reflecting Medicines Australia's recommendations in the 2016-17 Budget will benefit:

- *Consumers*, through providing early access to innovative treatments,
- *Government and taxpayers*, by utilising ongoing savings reforms and recognising the broader, innovative value of medicines; and
- *The wider community*, by strengthening employment within a high-quality and innovative manufacturing sector, as well as allowing consumers to more directly contribute to the economy and their local community.

The recommendations made within this submission, if implemented, will continue to drive innovation in the pharmaceutical industry, strengthen global and local confidence in the Australia's business productivity, and will lead to a stronger pharmaceutical industry contribution to the Australian economy at a time when investment and growth are critical.

We can have a world class medicines system that delivers for the community, encourages investment, and has benefits for the broader economy through things such as productivity improvements and a healthier society.

Over coming weeks Medicines Australia will seek to meet with appropriate officers within the Departments of Prime Minister and Cabinet, Treasury and Finance to discuss these points with you further, and answer any questions you may have.

## APPENDIX A

### The Impact of PBS Reforms on the Innovative Pharmaceutical Industry in Australia

The Industry requires a period of stability and predictability to manage the ongoing implementation and impact of significant reforms so that we can continue to deliver value and innovation to the Australian community.

Medicines Australia acknowledges the budgetary challenges facing the Government. There are also unique, ongoing pressures to funding high quality health services, including innovative medicines and vaccines with a growing and ageing population.

Innovative medicines and vaccines can help to alleviate the pressure on some areas of Government expenditure by helping to keep people healthy, working and paying taxes. However, these medicines do come at an upfront cost that reflects the investment in R&D necessary to bring these products to patients that needs to be met.

Treatments for disease are improving all the time. They are more personalised, potentially more expensive but more effective and provide more cost effective value for each dollar spent.

Medicines Australia has acknowledged these challenges, and sought to partner with Government for some time. 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>22</sup>. In addition, the Government announced a further \$6.6 billion worth of savings (\$3.7billion net) in May 2015 as part of the 6<sup>th</sup> Community Pharmacy Agreement and PBS Access and Sustainability Package (PASP).

The 2015 MYEFO update has revealed further higher than expected savings from existing pricing policies, with \$549m in reduced PBS payments. This reduction is expected to be up to \$1.6 billion over 4 years to 2018-19.

This approach sends a critical signal that Australia values innovation and wants to be part of the global innovation investment chain and the benefits that this brings.

Australia is in a global, highly competitive market for these valuable investment dollars that pharmaceutical companies deliver for R&D, Clinical Trials, to partnerships with local Universities, Biotechs and other specialised industries such as manufacturing and engineering.

#### Local Trends since PBS reforms began in 2007

##### Reduced Jobs:

The trend for employment in Australia's innovative pharmaceutical industry is in decline. Following a peak of 15,400 workers directly employed by the industry in 2012-13, there have been more than 1,200 job losses, with hundreds more job cuts forecast in the short term following the pricing policy changes announced in 2015.

##### Continuing changes in Pharmaceutical Manufacturing:

Australia's pharmaceutical manufacturing industry is in transition. There has been a lot of change to the type of manufacturing over the last decade. Australia is losing older-style product manufacturing to Asia, however, there remains some strengths in Advanced Manufacturing where Australia continues to compete for investment in local facilities.

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<sup>22</sup> <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20130515-rep-The-Impact-of-Further-PBS-Reforms-Final-report-from-CSES.pdf>

Since 2007, six member companies have announced closures or partial closures of their manufacturing operations in Australia. Some companies such as CSL have made public their decision to overlook Australia for new product manufacture in favour of Switzerland due to its attractive policy, tax and operating settings<sup>23</sup>.

#### Continued decline of Pharmaceutical Exports:

Pharmaceutical exports were once an Australian success story. From July 2009 to July 2014, medicines and vaccines were Australia's largest manufactured export ahead of the car industry and wine. At the beginning of 2013 pharmaceutical exports were more than \$4 billion per year. However, today exports are worth approximately \$2.5 billion annually. This sharp decline included a 30% fall in the first half of 2015. Pharmaceutical exports have now dropped below the car industry and on current trends will shortly fall to third behind wine.

#### **The effects of 2015 PBS policy changes and associated savings of \$6.6 billion (\$3.7 billion net) through the PBS Access and Sustainability Package (PASP) are having an impact on our members' Australian investments.**

Medicines Australia member companies have already begun to feel the impacts of the PASP reforms (Table A1).

**Table A1: PASP Reform Measures**

- One-off statutory price reduction of five per cent for all medicines in the F1 formulary (on patent drugs) after they have been listed on the PBS for at least five years.
- Removing the originator brand from the Price Disclosure calculation after 6 cycles
- Increasing the number of price change points from 3 to 6 per year
- Flow-on price disclosure reductions from single ingredient medicines (e.g. atorvastatin) to combination items (e.g. amlodipine and atorvastatin).
- Savings generated from the uptake from Biosimilars
- Expanding the list of medicines covered by the 20 Day Rule
- Removing (Delisting) OTC Medicines from the PBS (Revised PBAC exclusions)
- Refocussing the Premium Free Dispensing Incentive (PFDI) fee to only apply where there is a brand premium
- Maintain current funding levels for the Community Services Obligation (CSO), with a freeze to current indexation
- Provision of National Diabetes Services Scheme (NDSS) Products through the CSO
- Allowing Pharmacy to Discount the PBS Patient Co-payment to customers

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<sup>23</sup> Tax Competitiveness for Advanced Manufacturing the key to commercialising Australian R&D. CSL 2015. <http://www.csl.com.au/s1/cs/auhq/1187378853299/news/1252900902983/prdetail.htm>

A recent survey of our members has revealed that even at the early stages of the implementation of the reforms, there is an impact on jobs, investments, clinical trials and other R&D programmes. Regrettably, there is the potential for existing products to be removed from the Australian market due to some of the pricing policies, while some new products may no longer be brought to Australia in the near future due to the erosion of the price of comparator products.

The impacts resulting from the 2015 PBS changes are yet to be identified or realised, however the ongoing uncertainties created by these recent cuts have sent a poor signal to our member companies' overseas headquarters about the business and investment environment in Australia.

### **Examples of the impact on MA Members from the 2015 PBS policy changes**

An ongoing survey of our members is already revealing the impacts of the 2015 Budget decisions related to the PBS.

#### Jobs:

Already more than 150 job losses have been identified by MA members including:

- At least three companies that will retrench a third of their workforce; in one case this will be more than 50 jobs lost at the company.
- Three surveyed companies will each cut 60+ jobs
- 21 Redundancies were announced at Janssen in October 2015 due to the “volatile environment”<sup>24</sup>
- 14 jobs were lost at Novo Nordisk in November 2015<sup>25</sup>

#### Access to latest innovative medicines:

Several members have highlighted that the ongoing pricing policy changes for the PBS will see the entry of new medicines either further delayed or not enter Australia at all.

- Specifically a number of companies have warned that access to new cancer, Alzheimer and anti-depressant treatments could be further delayed or not listed on the PBS at all.
- In one case, and illustrative of the concerns with current pricing policies, a company has decided not to seek listing a new, innovative treatment because the price offered in Australia is the second lowest in the world due to severe price reductions to its comparators.
- Some medicines face removal from the market altogether due to changes to the price disclosure calculations, where by originators will be removed from the Weighted Average Price Disclosure (WADP) calculations. This policy may have several unintended consequences for supply, including subsidies falling below the cost of supply, as it fundamentally distorts the reimbursed market level.

#### Clinical Trials:

The 2015 PBS policy changes will have an impact on clinical trials in Australia, according to our surveyed members.

- One company has already identified a reduction of 50-60% in its clinical trial investment in Australia.

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<sup>24</sup> <https://pharmadispatch.com/news/volatile-market-hits-janssen-jobs>

<sup>25</sup> <https://pharmadispatch.com/news/novo-nordisk-the-latest-to-announce-job-cuts>

- Many others surveyed have identified a direct correlation between pricing unpredictability, PBS listing delays and its ability to win clinical trial investment in Australia from within their global company.
- One company says 10 trials in its global pipeline are no longer earmarked for Australia.

#### R&D Investment:

The pharmaceutical industry is one of the biggest investors in R&D in Australia with Investment in R&D by our members has averaged around 10% of sales revenue in Australia. For some companies it can be as high as double that percentage. In our internal survey of the 2015 PBS changes, many companies have identified the negative impact on R&D investment resulting from Government pricing policies.

While it is not the only factor considered when making R&D investment decisions, there is often a link between local sales revenue and the countries attractiveness as an investment destination. Many members expect there to be a decline in R&D investment in Australia by their global companies in the near future.

#### **Price Disclosure – A Case Study of Policy Impacts on Industry**

Price disclosure commenced in August 2007 with the aim of achieving savings in the F2 formulary through market competition between multiple brands of drugs.

In its report to Parliament in 2010 titled, *The Impact of PBS Reform, Report to Parliament on the National Health Amendment (Pharmaceutical Benefits Scheme Act 2007)*, the Government indicated that the total savings due to price disclosure from 2008-09 to 2017-18 would be between \$2.2 billion to \$4.4 billion.

A 2013 report from the Centre for Strategic Economic Studies (CSES), titled *The impact of Further PBS Reform*<sup>26</sup> predicted that total savings from the 2007 and 2010 PBS reforms, including the price disclosure policy, would actually be in excess of \$ 18 billion between 2007-2017/18.

Since the introduction of this policy, successive Governments have modified price disclosure to extract even more savings. When the former Labor Government modified price disclosure in 2013 moving the price disclosure cycles from 18 to 12-months, an additional \$835 million in savings were achieved over the forward estimates. This combined with larger than expected savings from price disclosure has culminated in over \$20 billion worth of savings expected during the period 2007-2017/18.

This is in addition to the \$6.6 billion of savings (\$3.7 billion net) announced in the PASP. In recent years the Government has also tended to over forecast expenditure on the PBS, and this appears to still be the case as outlined in the 2015-16 MYEFO with \$1.6 billion in addition savings over the forward estimates reported<sup>27</sup>.

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<sup>26</sup> <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2010/01/20130515-rep-The-Impact-of-Further-PBS-Reforms-Final-report-from-CSES.pdf>

<sup>27</sup> <http://www.budget.gov.au/2015-16/content/myefo/html/index.htm>