

***We develop innovative medicines for patients which allows the Australian Government to invest in a healthier Australia.***

## EXECUTIVE SUMMARY

### Recommendation

***In recognition that enduring savings measures and ongoing, sustainable and structural reforms have been implemented in the PBS:***

***Medicines Australia recommends that the offset policy for new listings on the PBS be removed, to meet the anticipated needs and expectations of Australian patients.***

Medicines Australia is pleased to put forward its 2020-2021 Pre-Budget Submission. Medicines Australia and its members are seeking to continue our collaborative partnership with the Australian Government to ensure that Australia's first-class health care system can continue to deliver lifesaving and life changing medicines to Australian patients.

This Pre-Budget Submission outlines the opportunity that Medicines Australia has identified for the Government to continue to meet its commitment to list all medicines recommended by the Pharmaceutical Benefits Advisory Committee (PBAC). Our recommendation, to remove the offset policy for new listings on the Pharmaceutical Benefits Scheme (PBS), will strengthen the Government's ability to maintain the significant health and economic benefits that the PBS delivers to Australians.

For over 10 years, the partnership between the Government and the pharmaceutical industry through Medicines Australia has resulted in a sustainable PBS for Government, through the introduction of structural and enduring pricing policies that continuously generate savings. These abiding measures include the introduction of cost-effective technology assessment; expanded, accelerated and simplified price disclosure; post market reviews; staggered statutory price reductions; price disclosure and reference pricing policies; as well as collaborative bilateral price negotiations between sponsors and the Government.

These savings reforms are implemented in addition to offset policy austerity measures introduced by the then Labor Government during the sluggish economic conditions of the Global Financial Crisis (GFC). The continuation of savings reforms alongside more recent improved economic growth has led to a structural decline in the PBS.

This has resulted in flat growth and decreasing net PBS expenditure as a proportion of the national GDP. Meanwhile, the overall health budget has increased, and this has resulted in the health budget proportion of GDP also slightly increasing.

The co-creation of a PBS with savings measures has met the needs of Australian patients, but Australia faces the pressure of a growing and ageing population. These pressures can be compensated, and this can be achieved without further direct offsets or new savings measures.

Medicines are an essential component of healthcare and play a vital role in ensuring Australians live longer and healthier lives; can remain in the workplace, out of hospitals and positively contributing to the community and the economy. Every innovative medicine made available in Australia generates a significant return on investment – to the patient, the community, the economy and the Government.

Medicines Australia welcomes the Government's renewed commitment to list all positive PBAC recommendations on the PBS and is calling for Government to continue this commitment to ensuring Australians have access to medicines in line with expected population demands.

## INTRODUCTION

The pharmaceutical sector, through Medicines Australia, has contributed to pricing reforms with successive governments since 2010,<sup>1</sup> that have allowed the Minister to commit to listing all medicines recommended by the PBAC. The result of these iterative, industry-government reforms, and the ongoing partnership, has ensured predictable PBS expenditure during times of wider fiscal constraint.

Through the ongoing partnership with the Government and its Departments, Medicines Australia has continued to work towards improvements to the Therapeutic Goods Administration (TGA) and PBS regulatory processes. These improvements build on Australia's reputation in providing timely registration and affordable universal medicines access to all Australians, regardless of their geographical location or financial situation.

In recent years, and for the foreseeable future, a host of medical and medicine innovations have and will become available, changing how diseases will be treated in the future.<sup>2</sup> These incredible advances will disrupt and challenge the health system as we know it.

## Policy Rationale

Medicines Australia's collaboration with the Government to ensure that Australians have access to new and emerging therapies. This requires a predictable and sustainable reimbursement system and an ongoing commitment to ensuring access to medicines for an aging and growing population.

Medicines Australia has analysed the future projections of population growth and ageing, as well as the current strong commitment to listing new medicines and compared it to the current levels of PBS expenditure. Within an environment of government offsets and enduring savings reforms our analysis indicates the pressures of population changes and listing commitments can be achieved by the removal of the offset policy for new listings, and without the need for any new savings measures.

Medicines Australia believes the effectiveness of current savings measures has provided fiscal headroom, and new medicines can be listed through an estimates variation. This will help the Government meet imminent population demands and listing commitments.

## Investment to Keep Pace with Community Needs

Medicines Australia strongly supports the Government's commitment to list all positive PBAC recommendations. This confirms the Government's recognition of the importance of timely access to new treatments for better health outcomes and choice. Medicines Australia's submission supports the Minister for Health and the Health Department's quest to continue to deliver on this promise and we are encouraging the Government to make further, continued investment in medicines a priority for the future, so that Australians continue to benefit from new discoveries.

Medicines Australia's analysis (below) indicates that the current PBS structure will struggle to meet the ongoing needs and expectations of the Australian community. This is exacerbated as the investment in net PBS expenditure, as a proportion of GDP, continues to decrease into the forward estimates, while pressure on the PBS increases with emerging breakthrough medicines, and a growing and ageing population.

Medicines Australia has reviewed PBS expenditure from the last decade and estimates that to meet the future needs of Australia's ageing and growing population, and to continue to achieve the equivalent access to medicines that we have today, a commitment to the PBS as seen a decade ago (in terms of proportion of GDP and total health budget) will be needed.

Our analysis shows that to meet the anticipated needs of the Australian population, PBS expenditure of at least \$685 million per year over the forward estimates (compound rate of 5.69% pa) will be necessary.

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<sup>1</sup> Memorandum of Understanding 2010; between Medicines Australia and the Commonwealth Government; PBS Access & Sustainability 2015; Strategic Agreement 2017; between Medicines Australia and the Commonwealth Government

<sup>2</sup> Example, Chimeric antigen receptor, or CAR T-cell therapy, Kymriah® (tisagenlecleucel)

However, we emphasise that the continuous, ongoing savings being delivered through enduring savings measures, mean that there can be an immediate reconsideration of the Government's current policy requirement for equal offsets to match new expenditure for new medicines, as these are not required in the current context.

This will improve Government's flexibility to manage PBS expenditure, as and when it is needed, to continue to meet its commitment to list all medicines that have received a positive PBAC recommendation. Ongoing consideration of innovative approaches that ensure universal, subsidised access to medicines should continue to be explored in the medium to long term.

## A Sustainable PBS

There is no other Government funded program with a range of measures which apply to it like the PBS. Since 2010, multiple reforms and policies have been implemented, so that enduring savings measures are built into the system. This delivers a fiscally self-sustaining and reliable PBS in terms of overall expenditure (net of rebates).

The PBS is divided into two formularies; F1 for new, single brand medicines, and F2 for multiple brand medicines (such as generics). The requirement for rigorous cost effectiveness analysis of new (F1) medicines, through health technology assessment, ensures value for money for the Government. This is further enhanced by the subsequent impact of ongoing savings measures for all medicines, in F1 & F2.

For example, Medicines Australia's Strategic Agreement with the Commonwealth (2017)<sup>3</sup> includes regular, 'anniversary', statutory price reductions applied to medicines every five years after listing on the PBS, and when generic medicines enter the market. These legislated price reductions provide ongoing headroom for listing new medicines.

Furthermore, mandatory price disclosure in the multi-brand formulary (F2) provides continuous and significant savings to Government from competition in the off-patent market. Ongoing market driven price disclosure reductions have resulted in many medicines being below the co-payment for non-concession holders and no longer requiring government subsidy.

Additionally, existing reference pricing policies ensure that medicines approved on a cost-minimisation basis do not add cost to Government expenditure, and any lower price offers flow through to all reference-linked medicines, delivering even greater value and more savings, to the Government.

Finally, bilateral negotiations between the Department of Health and manufacturers frequently include risk-share arrangements that provide predictable, contained PBS spending on a case by case basis.

These types of savings policies are not seen in other areas of government spending, and have achieved higher than expected and enduring offsets, for a sustainable PBS. This built-in sustainability has helped the Government to list all medicines that have received a positive PBAC recommendation and uphold its commitment.

## The Impact of Investment in Medicines

Medicines are an essential component of healthcare and help Australians live longer and healthier lives; remain in the workplace, out of hospitals and positively contributing to the community and the economy. The innovative pharmaceutical industry contributes to the health and wealth of Australia, providing new treatments to save and improve people's lives. Every innovative medicine made available in Australia generates a significant return on investment to the patient, the community, the economy and the Government.

The industry further contributes to the Australian economy by undertaking business, investing in bench-top and clinical research, and in local manufacturing, partnering with research organisations and

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<sup>3</sup> Strategic Agreement, Commonwealth of Australia and Medicines Australia Ltd. Clause 5, 2017;  
<https://www1.health.gov.au/internet/main/publishing.nsf/Content/landmark-compact-Medicines-Aust>

sharing research throughout the wider ecosystem.<sup>4</sup> In 2016 it was estimated that the industry contributed over \$8.9 billion to the economy and supported 22,900 FTE jobs.<sup>5</sup>

Adopting medical advancements is a vital step for Australia; innovation has a substantial role to play in the evolution and sustainability of our health system. There are monumental shifts taking place in the way diseases will be treated and their consequential positive impacts. We must ensure we have the right systems in place to provide the best healthcare outcomes in this rapidly changing environment. Our members have brought many innovative advances to Australia. These few examples below show why the PBS was designed as an uncapped program to ensure that there are no barriers to the introduction of new therapies in Australia that have a positive impact on patients, the community and the Government.

A new treatment recently listed by the Government is Tafinlar® (dabrafenib) and Mekinist® (trametinib) for post-surgery treatment of patients who have Stages IIIB-D melanoma. Melanoma is the third most common cancer in Australia for both men and women.<sup>6</sup> This combination therapy has shown significantly improved survival and delayed drug resistance over the use of a single agent for those with the BRAFV600 mutation, and its listing saves over \$128,900, based on list price, for over 260 patients per year.<sup>7</sup>

Lost wages now account for just one third of the total economic burden, compared to half seven years ago, thanks to advances in medical treatment. For example, Symdeko®, listed on the PBS from 1 December 2019 for patients with cystic fibrosis over the age of 12 with specific gene mutations, could add an estimated 20 years to recipients' lives.<sup>8</sup>

The listing of a number of Hepatitis C treatments since 2016 is another example of medicines making a difference. In order to make these treatments available, the government is investing more than \$1 billion over a five-year period to treat the 230,000 Australians living with the disease. As a result of this listing, Australia is a leading country in the global response to Hepatitis C. Around 40,000 people have had treatment with an estimated 95% cured, avoiding disease progression and additional costs.<sup>9</sup>

These examples demonstrate the direct connection between the listing of innovation and benefits to the health and wellbeing of Australians. However, broader economic benefits from the listing of these medicines also offset costs across the wider government budget. The cost of early retirements on GDP was estimated to be \$45.3 billion in 2017 and expected to increase to \$53.4 billion in 2025. Effective health programs, such as listing of new medicines, can reduce these costs by up to 20%.<sup>10</sup>

Similarly, Australians lose \$20.8 billion in superannuation each year from early retirement due to ill health – but health strategies that include new classes of medicines to treat chronic disease could recover as much as \$1.9 billion in superannuation and return \$3.9 billion to the economy.<sup>11</sup> Medicines Australia believes that supporting Australians to extend their capacity to work should be a priority.

Finally, new medicines help reduce the days of hospital care for Australians, helping to reduce hospital expenditure. It is estimated that hospital expenditure in 2015 was reduced by \$3.47 billion because of

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<sup>4</sup> MTPConnect MedTech and Pharma Growth Centre reports: Clinical Trials in Australia, <https://www.mtpconnect.org.au/clinicaltrials>; How Global MedTech & Pharma Corporates Engage with Australia, [https://www.mtpconnect.org.au/Category?Action=View&Category\\_id=203](https://www.mtpconnect.org.au/Category?Action=View&Category_id=203).

<sup>5</sup> PwC Consulting, 2017. The economic contribution of the innovative pharmaceutical industry to Australia. Report commissioned by Medicines Australia.

<sup>6</sup> Melanoma Institute Australia, *Melanoma Facts and Statistics*, <https://www.melanoma.org.au/understanding-melanoma/melanoma-facts-and-statistics/>. Accessed 10 November 2019

<sup>7</sup> <https://www.greghunt.com.au/pbs-listings-to-save-melanoma-and-multiple-sclerosis-patients-up-to-128900-a-year/>. Accessed 10 November 2019.

<sup>8</sup> <https://www1.racgp.org.au/newsgp/clinical/cystic-fibrosis-drug-listed-on-pbs/>. Accessed 10 November 2019.

<sup>9</sup> <https://theconversation.com/australia-leads-the-world-in-hepatitis-c-treatment-whats-behind-its-success-81760>. Accessed 10 November 2019.

<sup>10</sup> 2018, The McKell Institute, *'Our Health Our Wealth, The Impact of Ill Health on Retirement Savings in Australia'*, Accessed 5 December 2019: <https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/09/Our-Health-Our-Wealth-full-report.pdf>, sponsored by Medicines Australia, 2018.

<sup>11</sup> Ibid.

planned investment in medicines in the decade prior.<sup>12</sup> These examples demonstrate the true value of the PBS, and why investment in medicines has a significant positive influence on the economy.

## The PBS Today and into the Future

The PBS is already delivering excellent health outcomes for all Australians. But like all national programs, it needs to be modernised and refined to ensure that it is delivering the most up-to-date health care to meet modern health challenges, which includes high quality medicines and cutting-edge treatments.

Current net PBS expenditure is much lower than the headline figure reported when discounts, paid by companies in the form of rebates back to Government, are accounted for. This has resulted in flat PBS expenditure over the decade, which is expected to continue over the forward estimates, with growth in the PBS estimated to be at 0.06%. This nominal growth puts Australians' universal access to medicines, and the Government's commitment to list all medicines, at risk due mainly to three factors:

1. A growing population;
2. An ageing population (65+) who comprise the largest proportion of the population requiring access to PBS medicines. (By 2025 more than 17% of Australians will be 65+, as opposed to 11.6% in 2011)<sup>13</sup>, and;
3. The current trends in new and expanded medicines (F1 medicines) being added to the PBS as new treatments, and the trends in generic medicines available for existing treatments (F2 medicines).<sup>14</sup>

When compared to Australian Bureau of Statistics (ABS) population growth projections, current PBS expenditure will not be adequate to account for the medicines needs of a growing population. Investment in the PBS needs to increase by a compound rate of least 1.64% per year at a minimum just to account for this.

As shown in the Department's *Trends in and drivers of Pharmaceutical Benefits Scheme expenditure report 2013* the 65+ age group is now the majority of the users of PBS medicines. Taking into account the population growth in this age group, and their increasing proportion of medicines use, investment in the PBS would need to grow at a compound rate of least 2.43% per year.

Looking at the *National Health (Listed drugs on F1 or F2) Determination 2010* legislation, trends of new F1 Listings and movements from F1 to F2 can be identified. Based on historical trends of new listings and movements from F1 to F2 from 2010-11, PBS investment would need to increase at a compound rate of 5.69% per year, or at least an additional \$685 million per year over the forward estimates to ensure continued access to these innovative treatments - if trends remain similar.

Importantly, this analysis assumes there is no change in the proportion of PBS expenditure directed to the distribution and dispensing of medicines. Up to one third of PBS expenditure is attributed to the supply chain, distribution and dispensing, of medicines to the point of patient access.<sup>15</sup> If any change to these costs were agreed through government/industry negotiations, such as the Community Pharmacy Agreement (7CPA), then the investment required to meet community demand would need adjustment.

## PBS as a proportion of GDP

While expenditure on the PBS has grown slightly, expenditure as a proportion of GDP has fallen. Figure 2 shows PBS expenditure as a proportion of national GDP, including estimated decline over the forward estimates, and adds potential growth projections based on the three factors detailed above.

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<sup>12</sup> 2019, Lichtenberg F. *The Impact of Pharmaceutical Innovation on Premature Mortality & Hospitalization in Australia 1998-2018*.

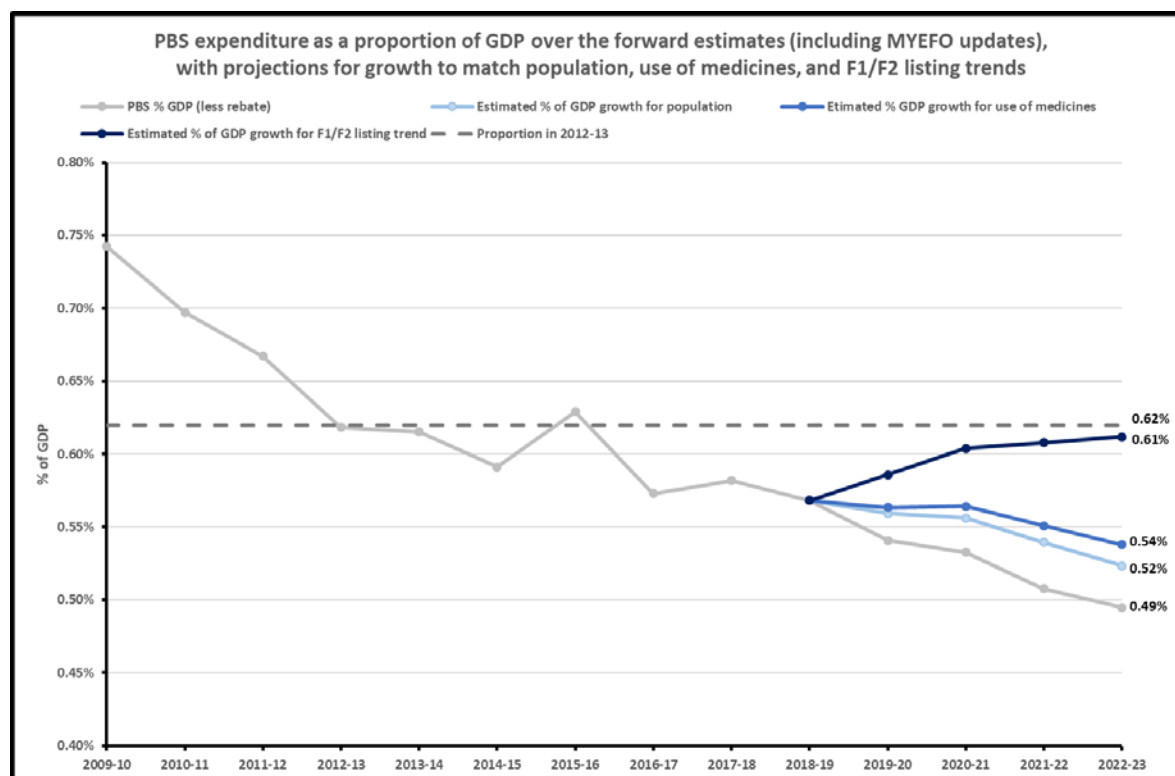
<sup>13</sup> AIHW, 2018, Older Australia at a Glance. Accessed 10 November 2019: <https://www.aihw.gov.au/reports/older-people/older-australia-at-a-glance/report-editions>.

<sup>14</sup> Medicines listed on the 'F1' Formulary are medicines that are a single brand and do not have generic copies. When a generic medicine enters the system both the generic copy medicine and the original medicine brand are listed in the 'F2' formulary.

<sup>15</sup> Review of Pharmacy Regulation and Remuneration; <https://www1.health.gov.au/internet/main/publishing.nsf/Content/review-pharmacy-remuneration-regulation>

PBS expenditure (less rebates) as a proportion of the GDP has fallen from 0.74% in 2009-10 to 0.57% in 2018-19 and is projected to continue to fall at the current rate of investment, as shown in Figure 2.<sup>16</sup> Using the projections of GDP growth presented in the 2019-20 Budget,<sup>17</sup> PBS expenditure as a proportion of GDP is projected to fall significantly at an annual rate of 3.39% over the forward estimates. This would see PBS expenditure at only 0.49% of GDP by 2021-22.

**Figure 1: PBS expenditure as a proportion of GDP over the forward estimates, with projections for growth to match population, use of medicines, and F1/F2 growth trends**



Projections added to Figure 1 also show what the proportion of PBS expenditure would be if expenditure over the forward estimates was adjusted to account for a growing population; growth in the 65+ population that is using the majority of medicines; and on current F1/F2 listing trends.

**Table 1<sup>18</sup>: OECD proportion of GDP allocated to pharmaceutical program\***

Country	2014	2015	2016	2017	2018	2019
Canada	1.74%	1.82%	1.83%	1.79%	1.80%	N/A
Germany	1.57%	1.59%	1.61%	1.58%	N/A	N/A
Japan	2.04%	2.15%	2.01%	N/A	N/A	N/A
GBR	1.14%	1.14%	1.14%	1.15%	N/A	N/A
Australia (OECD)	1.30%	1.35%	1.36%	N/A	N/A	N/A
Australia (FBO, less rebate)	0.62%	0.59%	0.63%	0.57%	0.58%	0.57%

\*N/A = Not available

<sup>16</sup> Source: Final Budget Outcomes various years, Department of Health Annual Report various years, 2019-20 Federal Budget forward estimates, ABS catalogue 5206.0 GDP figures, ABS catalogue 3222.0 population projections, Department of Health Trends and Drivers of PBS expenditure 2013, National Health (listed drugs on F1 or F2) Determination 2010, various months.  
<sup>17</sup> In the 2019-20 Mid-Year Economic and Fiscal Outlook GDP growth in nominal terms is projected to be 5.3% in 2018-19, 3.25% in 2019-20, 2.25% in 2020-21, and 4.75% in 2021-22 and 2022-23.

Increases in expenditure to account for demographic changes would still see a fall in the proportion of the GDP invested in medicines. However, if PBS investment over the forward estimates was revised to the rate of growth estimated on historical F1 and F2 listing trends, PBS expenditure would be equivalent to the level it was from 2013-14 to 2015-16 by the end of the forward estimates period.

Table 1 shows that Australian rates of PBS expenditure (less rebates) are much lower than many overseas comparisons. Even with an additional growth in the PBS to allow for the predicted demand as listed above, it can be seen that overall Australia’s position is such that it is still delivering exceptional value for money when it comes to investing in medicines, and is comparable to similar countries.

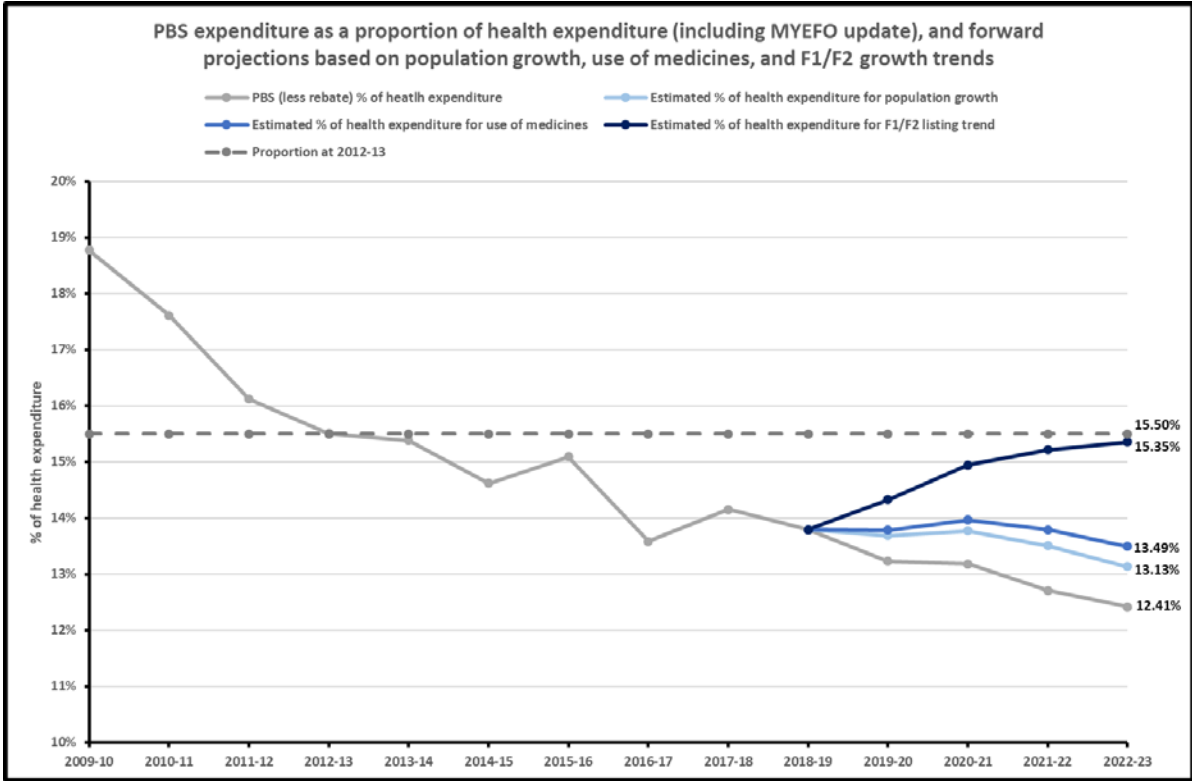
### PBS as a Proportion of Health Expenditure

Similar to the trends seen in PBS expenditure as a proportion of GDP, the same can be seen when PBS expenditure is compared to overall health expenditure. Australia has enjoyed strong GDP growth over the decade, at an average rate of over 4%. Health expenditure as a proportion of GDP has also grown just as strongly, at a slightly higher rate over this same time period.

Figure 2 shows PBS expenditure as a proportion of overall health expenditure, including projections over the forward estimates, and comparisons to the growth scenarios presented above. PBS expenditure (less rebate) as a proportion of the overall health expenditure has fallen over the decade from 18.77% in 2009-10 to 13.79% in 2018-19.<sup>19</sup>

Using the projections of overall health expenditure presented in the 2019-20 Budget, PBS expenditure as a proportion of overall health expenditure is forecast to fall at an annual rate of 2.59%, dropping to a projected 12.41% in 2021-22.

**Figure 2: PBS expenditure as a proportion of health expenditure, and forward projections based on population growth, use of medicines, and F1/F2 growth trends**



<sup>19</sup> Source: Final Budget Outcomes various years, Department of Health Annual Report various years, 2019-20 Federal Budget forward estimates, ABS catalogue 3222.0 population projections, Department of Health Trends and Drivers of PBS expenditure 2013, National Health (listed drugs on F1 or F2) Determination 2010, various months.

Increases in medicines investment to account for demographic changes would still see the proportion of health expenditure fall over the forward estimates. However, if PBS investment over the forward estimates was revised to the rate of growth based on historical F1 and F2 medicine listing trends, PBS expenditure as a proportion of would be the equivalent to levels seen in 2012-13 by the end of the forward estimates period.

## CONCLUSION

Government investment in medicines via the PBS reduces the burden of disease and improve the lives of numerous Australians. There are a wide range of innovative medicine companies that are developing new medicines and treatment therapies already in the pipeline. Recent history from a range of new medicines shows us how effective direct medicine investment can be. Like all national systems, the PBS needs to be improved and modified to ensure that it delivers the best, most up-to-date health care, to meet Australian health challenges. Now is the time to plan for the next stage of developments, including those targeting age-related diseases such as coronary heart disease and dementia,<sup>20</sup> and transformative whole-of-life changes for children diagnosed with potential life-long disease.

Australia's PBS has delivered universal access to medicines for Australians for 70 years and continues to do so in a fiscally self-sustaining manner. It has helped to improve the health and well-being of many Australians. In return the Government has been repaid with increased productivity and broader economic prosperity, contributing to Australia's strong economy.

However, medicines investment over the forward estimates show that investment levels risk falling behind a growing and ageing population, and current trends in F1 and F2 medicines listings.

In recognition of the enduring savings and ongoing sustainable and structural reforms that have been implemented and delivered a sustainable PBS; and to ensure Australians can continue to have access to the latest, high-quality medicines and cutting edge treatments made affordable by the PBS; the listing of new medicines be exempt from the requirement to find new offsets.

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<sup>20</sup> AIHW, 2018, Older Australia at a Glance. Accessed 10 November 2019: <https://www.aihw.gov.au/reports/older-people/older-australia-at-a-glance/report-editions>