

2023-24 Pre-Budget Submission

COVID-19 caused significant disruption to historic patterns of growth in the Australian economy. With COVID-19 related restrictions and health measures lifted, economic growth has begun to return to longer-term patterns. The pace of inflation and the cost of living will no doubt draw much of the focus for the year ahead but there is still work to be done sheltering the economy from the ongoing effects of the pandemic.

‘Living with COVID’ is now a term many Australians are familiar with. The term engenders a sense of comfort that the worst of the pandemic is behind us, but it belies the fact that the pandemic is not over. Ongoing risks include the continued emergence of new variants, declining rates of ongoing vaccination compared to primary course vaccination rates and ensuring appropriate access to and uptake of antiviral treatments. If we fail on any of these fronts it could lead to ongoing high case numbers (higher hospitalisation rates and deaths), a rise in long COVID cases, higher healthcare costs, a rise in absenteeism and supply chain disruptions, which could undermine Australia’s productivity.

There is a need to remain COVID vigilant in 2023. Moving forward, it is critical to safeguard critical parts of our COVID-19 response – but that starts with following through with our response to COVID-19. This includes:

- Continuing to promote the importance of vaccination, at all stages of life.
- Ensuring a portfolio approach to vaccine and antiviral procurement as outlined in the Halton Review
- Better understanding long-COVID and taking steps to reduce the burden of long-term symptoms
- Trialling a novel reimbursement approach to combat AMR and to address the broken market for new antibiotics

Pfizer commends the Government on the release of the Wellness Budget Statement in 2022 which recognised the importance of measuring and benchmarking a broader range of social and environmental factors and to broaden the conversation about quality of life. Medicines and vaccines provide obvious benefits to the health of individuals - but as the last two years has demonstrated, they also make a significant contribution to productivity and societal well-being. The national vaccine rollout is an excellent example. Pfizer supported a recently released peer-reviewed policy research paper, which indicated that the timely rollout of COVID-19 vaccinations is estimated to have reduced the impact of the pandemic on the economy by \$214 billion, resulting in a positive incremental benefit of \$181 billion. This is evidence that the health of our nation, dictates the health of our economy and the critical role medicines and vaccines play in this regard.

The upcoming HTA review is a landmark opportunity that can lead to meaningful reform that ensures Australian patients have access to ground-breaking medicines and vaccines, at the earliest available opportunity. If this is to be the case, consideration needs to be given to the funding for innovative medicines and ensuring that the PBS and other envelopes for medicines and vaccines can accommodate new listings and meet the shared objectives of the Strategic Agreement.

Pfizer is a proud member of Medicines Australia, and we support their Budget submission which calls for the Government to lower the discount rate to 1.5% for vaccines and 3% for other medicines in this Budget. The next generation of medicines and vaccines will include more and more targeted, precision therapies and treatments for rare and complex conditions. If we do not move to reduce the base discount rate, we risk hindering access to several breakthrough therapies that could have lasting impact on the lives of Australian patients.

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Continued COVID vigilance: The ongoing importance of vaccines, a portfolio approach to procurement and reducing the burden of long covid

In 2023, far from it being the end of the pandemic, there is a new, dangerous phase that requires urgent attention. The emergence of new Omicron variants in the United States and United Kingdom and scenes of China's hospital system being overwhelmed with COVID cases is a stark reminder of the insidious nature of this virus and its continued threat to our way of life.

In Australia, case numbers are a far cry from the peak of this time last year, but at Christmas 2022 there were still 15,000 cases a day being reported nationally and the number of daily COVID related deaths has spiked again, tripling since November 2022 to more than 30 a day.ⁱ The majority of Australia's COVID-19 deaths occurred in 2022, for more than were recorded in 2020 and 2021.ⁱⁱ

Responding to the ongoing presence of COVID requires a continued vigilance and important steps can be taken to ensure Australia is ready to respond to evolution of the pathogen. This includes maintaining vaccination rates, particularly booster doses for those most vulnerable, a diversified 'portfolio' approach to procuring future vaccines and antivirals and better understanding and monitoring the impact of long COVID.

- **The ongoing importance of vaccines**

Reflecting on the end of 2021, Australia successfully opened its economy by becoming a vaccinated nation. That was an amazing achievement, and it required a collaborative approach from several contributors across the health sector.

However, since we reached the 95% two-dose COVID rate, it is fair to say that there has been a level of complacency and acceptance of COVID-19 within the community. Currently our national three-dose vaccine average is 72% and only 44% in those eligible for a fourth dose.ⁱⁱⁱ

We cannot take the focus off the importance of vaccines in seeing us turn the tide against COVID-19. The national vaccine rollout sheltered the economy from an even more devastating fallout. Pfizer supported a recently released peer-reviewed policy research paper which indicated that the timely rollout of COVID-19 vaccinations is estimated to have reduced the impact of the pandemic on the economy to an estimated \$214 billion, resulting in a positive incremental benefit of \$181 billion.^{iv} The rollout is estimated to have also contributed to large positive effects for tourism exports (\$28 billion) and education exports (\$26 billion), employment (142,000 jobs) and government finances (\$259 billion).^v

Without continued vaccination, the good work of the national vaccine rollout risks being undone. We will continue to see COVID-19 waves, and new variants, in turn impacting workplace absenteeism in critical services, which will directly impact Australians and the economy. Vaccines continue to be the best defence against the impact of COVID-19 and the severity of COVID-19 cases.

As we head into the autumn and winter period, we urge the Government to continue to promote the importance of vaccination at all stages of life, but particularly against COVID-19, and also to expand access to all vaccines through multiple front line health options as evidenced by the success of the COVID-19 vaccination in pharmacy program.

- **Maintaining a 'portfolio' approach to procurement and ensuring the global free movement of goods**

'We are unable to confidently predict the timing or impact of new waves and variants. This uncertainty presents particular challenges. The availability of efficacious vaccines and treatments will continue to play a key role in ensuring ongoing protection for lives and livelihoods.'^{vi} (Source: Review of Covid-19 Vaccine and treatment purchasing and procurement)

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The Halton Review into the procurement of Australia's COVID-19 vaccines observed that Australia's COVID vaccine rollout was on par with other advanced countries. However, the review strongly reinforced a portfolio approach to procurement 'will continue to be needed to mitigate the risk of supply shortage, delays, lack of success in clinical trials, manufacturing or regulatory failure.'^{vii}

Pfizer is proud of the role we played in responding to the pandemic. To date, we have delivered more than 3.8 billion doses of our COVID-19 vaccine to more than 180 countries worldwide. Working in partnership with the Australian Government, 75 million doses have been delivered to Australia, along with more than 1 million treatment courses of our COVID antiviral treatment Paxlovid®. During the pandemic we have also continued to supply essential medicines to State and Territory Governments to treat patients in hospitals.

Australia has placed an increased importance on sovereign capability and ensuring that future vaccine production can be onshore. Investing in advanced manufacturing and capability to meet future vaccination and protect against pandemic threats is understandable.

However, simply creating local manufacturing capability does not guarantee rapid and easy access to product. A recent paper from the Productivity Commission looking at Australia's five-year productivity recognises that 'pressures for greater self-reliance in the wake of the COVID-19 pandemic and geo-political disruptions pose significant risks to efficient investment and productivity growth.'^{viii}

The medicines manufacturing process depends on a complex global network of suppliers, competing for raw materials and equipment. Trade bottlenecks – including export restrictions, regulatory barriers, tariffs, and customs red tape – add uncertainty, cost and delay to both manufacturing and patient access.

In addition to investing in local manufacturing, Pfizer recommends strengthening programs and policies that enable the free movement of goods, particularly during times of crisis like the trusted trader program operated by the Australian Border Force.

What COVID-19 has laid bare is that Australia's island geography can serve as an advantage by using our borders to quarantine arrivals and protect the local population, but it also presents a significant challenge with intense pressure on supply chains into and out of the country in times of crisis.

If we are to take steps to make Australia more resilient in a global supply chain environment, there must be a recognition that ingredients and components of the end product come from many sources and have multiple conversion points from raw materials to finished product. Pfizer's COVID-19 vaccine for example consists of 280 components from more than 19 countries around the world.

In distributing our COVID-19 vaccine to countries around the world we have been clear with all stakeholders that the free movement of goods and supply across borders is critical to Pfizer and the patients we serve, particularly during this devastating global pandemic. The vulnerable supply chains inquiry from the Productivity Commission recognised that onshoring of manufacturing capability is a valid consideration but that prioritising sovereign capability over global supply can present risks to Government. The two issues are not mutually exclusive, and Australia should consider a diversified approach to ensure access to latest medicines and innovations.

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- **Reducing the burden of Long Covid**

Pfizer recently appeared with other medicines and vaccines manufacturers before the Senate Committee into Long-COVID and commends the Committee for investigation this important issue (our submission to the Committee is included as a supporting document to this submission).

The symptoms of Long-COVID are varied and wide-ranging and can lead to serious complications and have debilitating effects on adults and young people, affecting their ability to function in daily life, or perform daily activities, which in turn impacts their ability to work, leading to increase absenteeism and reduced productivity.^{ix}

Research using a retrospective matched cohort design during March 2020-November 2021 has indicated that one in five COVID-19 survivors may develop long COVID, rising to one in four in those who are over the age of 65 years.^x Based on a WHO estimate of 470 million worldwide COVID-19 infections, it is estimated that approximately 200 million individuals currently experience or have previously experienced long COVID.

The best way to prevent Long Covid is to avoid being infected with SARS-CoV-2 in the first place. Vaccines are a critical part of solutions to minimise disruption and mitigate uncertainty brought about by COVID-19. Pfizer would also echo our recommendations to the Senate committee which is in line with our advice to Government's around the world.

- Follow WHO and European Commission guidance^{xi, xii} and develop routine Long Covid surveillance systems and invest in multi-year studies to better understand Long Covid.
- Monitor the economic, productivity and long-term health consequences of COVID-19, in line with calls from the Institute of Fiscal studies in the UK.^{xiii, xiv}
- Promote immunisation at all stages of life by reviewing, protecting, and expanding budgets for COVID-19 and national immunisation plans.
- Follow the WHO prioritisation roadmap and vaccinate 100% of clinically vulnerable patients^{xv} against COVID-19 and look at increasing uptake of COVID antivirals.
- Continue to address vaccine confidence to help ensure high levels of uptake.
- We must also invest in healthcare infrastructure and strengthen COVID-19 immunisation programs to protect populations, healthcare systems and society at large from the long-term effects of SAR-CoV-2 infection

Antimicrobial resistance and the need for a novel approach to reimbursement

Antimicrobial resistance has been rising for years, but a spike in antibiotic use during the COVID-19 pandemic has accelerated the process. Studies of the use of antibiotics during the pandemic found that 60-70% of hospitalised COVID-19 patient received antibiotics, but very few COVID-19 patients were found to have primary or secondary bacterial infections, meaning most of the antibiotics used were unnecessary. Factors that led to this pattern of over-use of antibiotics included self-medication and the unavailability of rapid diagnostic tests. This pattern has led to increased multidrug-resistance and the worsening of resistance of strains already known to be difficult to treat.^{xvi}

The World Health Organisation has said that the global pipeline of antimicrobials is insufficient to tackle the increasing challenge of antimicrobial resistance.^{xvii} New antimicrobials are faced with very challenging access dynamics. To preserve their effectiveness for as long as possible, use is restricted through the important process of antimicrobial stewardship, hence volumes are low. They are also undervalued by traditional HTA techniques as it is difficult to economically evaluate the importance of holding new antimicrobials in reserve as well as the overall value of having a wide range of antimicrobials available to protect against outbreaks of resistant bacteria.

The threat of AMR on the future of our healthcare system cannot be underestimated. A study from the Lancet estimated that in 2019 there were 4.95 million deaths associated with bacterial AMR including 1.27 million deaths

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directly attributable^{xviii} and this figure is expected to worsen. AMR is on track to claim 10 million lives per year globally and put at risk a cumulative US\$100 trillion of economic output if no action is taken by 2050.^{xix} In Australia, the estimated annual impact of AMR on the economy by 2050 will be between A\$142 billion and A\$283 billion.^{xx} Australia is also vulnerable to novel antimicrobial shortages due to geographic isolation and the high costs and difficult logistics in international drug supply chains.

New antimicrobials are urgently needed to treat drug-resistant infections and the growing threat of AMR, however current regulatory and reimbursement policies deter investment in antimicrobial research. A novel policy response is required to encourage investment in this important research, to ensure the antibiotic pipeline is refilled to prevent the predicted AMR crisis.

Many countries are investigating how to assess the value of novel antimicrobials to include the broader value they bring to society. In the UK, the Government has partnered with industry to pilot a model of reimbursement that will de-link the revenue of an antimicrobial from the volume sold and base it instead on the antimicrobial's value to the NHS and wider public health. This means companies will be paid for antimicrobials based on how valuable they are rather than by the quantity being used or sold. This pilot will also help to reduce the financial uncertainty in antimicrobial research and elevate incentives to develop novel anti-biotics. Other countries including the US and Sweden are also progressing new models for the way they assess this class of medicine.

Pfizer is a member of the Australian Anti-Microbial Resistance Network (AAMRNet) and we fully support their position paper on the need for a novel reimbursement model to be trialled in Australia. This was also a key recommendation of the New Frontier's report from the house inquiry into novel medicines and medical technologies.

AMR is a global problem, and the situation is worsening. Australia can take a leadership position on this issue by introducing a novel reimbursement approach that appropriately values novel antibiotics and the broader economic benefits of reducing antimicrobial resistance.

[Key issues related to the Strategic Agreement between Medicines Australia and the Commonwealth](#)

[A fulsome HTA review and the need to invest in innovative medicines](#)

As part of the Strategic Agreement between the Commonwealth and Medicines Australia in 2021, the Federal Government will conduct an independent review of Australia's Health Technology Assessment (HTA) policies and methods. This is the most significant review of HTA policy and methods related to reimbursement of medicines and vaccines in almost thirty years.

Under the Strategic Agreement, the Commonwealth and Medicines Australia have the shared goals of:

- Reducing time to access for Australian patients so that they can access new health technologies as early as possible; and
- Maintaining the attractiveness of Australia as a first-launch country to build Australia's status as a world leader in providing patients access to affordable healthcare.

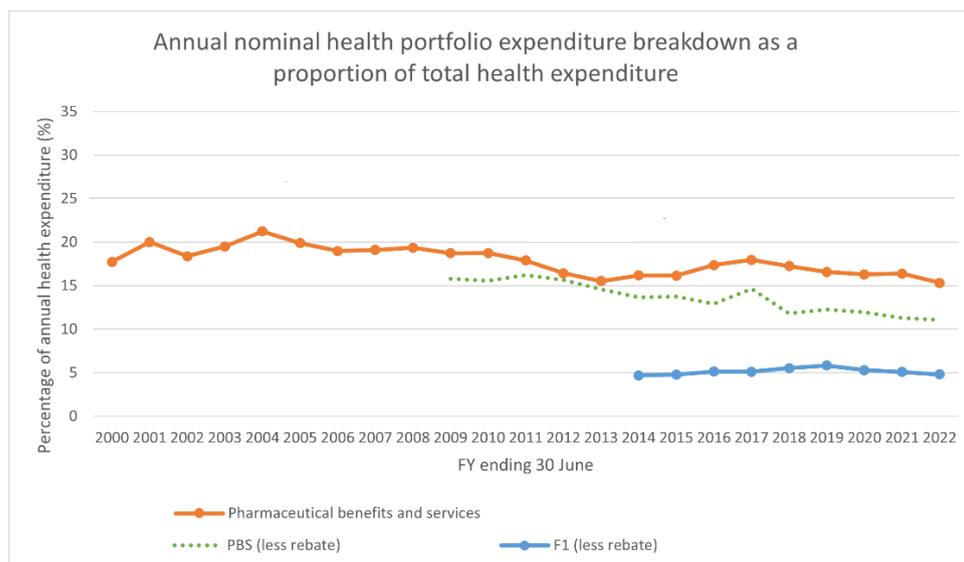
The HTA Review follows the recent revision of the National Medicines Policy and comes soon after the recommendations from the House of Representatives (HOR) Inquiry into the approval processes for new drugs and novel medical technologies included in the 'New Frontier' Report. The volume of submissions made to that Inquiry - the written and verbal testimony of patient groups, clinicians, and voices from across the medicines value chain - is the clearest indication yet that our system is not meeting the shared goals of the Commonwealth and Medicines Australia and a wide range of stakeholders, who believe significant reform is urgently needed.

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Pfizer believes it is imperative that the policy and methods review of HTA in Australia is comprehensive and conducted with full transparency, broad consultation, and adequate timelines. The terms of reference must encompass considerations of both policy and methods, meeting the shared goals of the Strategic Agreement and addressing the issues and community expectations detailed in the New Frontier Report. Publication of the Government response to the New Frontier Report without further delay is critical to ensuring the scope, conduct and outcomes of the HTA Review meet the expectations of the Australian community. The outcomes of the HTA review must lead to meaningful reform that ensures patients have access to ground-breaking medicines and vaccines, at the earliest available opportunity.

Without pre-empting the outcome of the review, if this is to be the case, consideration needs to be given to the funding for innovative medicines and vaccines, ensuring that the PBS envelope and other related budgets can accommodate new technologies and meet the shared objectives of the Strategic Agreement.

When reviewing Government expenditure on the PBS since the start of the century it is evident that savings measures, combined with the growth in rebates paid by companies have curtailed growth in the PBS. In fact, the PBS has been gradually falling as a share of GDP once rebates are considered, and today the PBS represents a smaller share of Commonwealth health expenditure than in 2000.^{xxi}



(Source: Shawview Consulting chart and analysis. Data sources: Department of Health and Aged Care, *PBS Expenditure and Prescriptions Report*, various years; <https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions>, Commonwealth of Australia, *Final Budget Outcome*, various years, www.budget.gov.au)

As this figure shows, the work the industry has done with consecutive governments over the last 20 years to minimise costs has provided financial headroom for future growth. The Pharmaceutical Benefits and Services share of health expenditure (before adjusting for rebates) has declined from over 20 per cent in 2004 to 15.3 per cent in FY2021-22, in large part due to the PBS reform packages negotiated between the industry and Commonwealth governments since 2004. Meanwhile, spending on F1 drugs (intended for single brand drugs) less rebates, has fallen below 5 per cent.^{xxii}

We are on the cusp of a new range of therapies and technologies that will require new thinking and adaptability to ensure that they are valued appropriately for manufacturers and government. Most importantly, we must ensure these medicines are available to the patients who need them, in a timely manner. Patients, their families and carers are more informed and empowered to take control of their own health; their demand for access to the latest interventions will only increase in the years ahead.

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To achieve this, HTA policies, methods and the associated methods should be reconsidered and updated, to ensure they are ready to accommodate this flood of innovation, particularly breakthrough medicines that achieve previously impossible outcomes. Future budgets also need provisions for real growth of the PBS over time and to recognise new and innovative medicines and vaccines as an investment in the health of Australians, and in turn, the health of our economy.

Support for Medicines Australia's Budget submission: Lower the discount rate at the 2023-24 Federal Budget

The Strategic Agreement also includes a commitment to review the PBAC base case discount rate against international health technology assessment (HTA) best practice and for any recommended change to be incorporated into PBAC guidelines by July 2022. Reducing the base case discount rate was also a bi-partisan election commitment from both parties.

In September 2022, the PBAC published the advice it provided to the Minister for Health and Aged Care on this issue, which accepted that a reduction of the discount rate is warranted. However, the PBAC also advised that any change to the discount rate be deferred and considered as part of the HTA review.

The current base case discount rate of 5% applied in Australia, is higher than several other comparable international jurisdictions and over the last 30 years, international discount rates have been trending downwards.^{xxiii} Using 5% as the base case rate means that Australia systematically undervalues vaccines, medicines and other novel treatments that have up-front costs and longer-term health benefits. In practice, the use of a higher discount rate means that Australians face delayed access to a range of vaccines and treatments and in some cases, reimbursed access does not occur at all. This is a particular concern for emerging cell and gene therapies that can dramatically alter the course of devastating and degenerative, life-long diseases.

Any delay to implementing the recommended change to the base case discount rate risks compounding this issue further. Pfizer supports Medicines Australia's submission to Government which asks the Government to lower the discount rate to 1.5% for vaccines and 3% for other medicines as part of the upcoming Budget.

ⁱ <https://www.health.gov.au/health-alerts/covid-19/case-numbers-and-statistics>

ⁱⁱ <https://www.abc.net.au/news/2023-01-20/covid-19-news-case-numbers-states-territories-january-20/101876004>

ⁱⁱⁱ <https://www.health.gov.au/sites/default/files/documents/2022/11/covid-19-vaccine-rollout-update-17-november-2022.pdf>

^{iv} Fox, Adams, Grainger, Herz & Austin (2022) The Value of Vaccines: A Tale of Two Parts – Vaccines, published Nov 2022

^v Fox, Adams, Grainger, Herz & Austin (2022) The Value of Vaccines: A Tale of Two Parts – Vaccines, published Nov 2022

^{vi} Halton (2022) Review of COVID-19 Vaccine and Treatment Purchasing and Procurement - <https://www.health.gov.au/resources/foi-disclosure-log/foi-4062-release-document-halton-review>

^{vii} Halton (2022) Review of COVID-19 Vaccine and Treatment Purchasing and Procurement - <https://www.health.gov.au/resources/foi-disclosure-log/foi-4062-release-document-halton-review>

^{viii} <https://www.pc.gov.au/inquiries/current/productivity/interim1-key-to-prosperity>

^{ix} <https://www.aihw.gov.au/getmedia/9592f439-9b96-4589-a55d-6b04e262e5e1/aihw-phe-318.pdf.aspx?inline=true>

^x Chen C, Haupt SR, Zimmermann L, Shi X, Fritsche LG, Mukherjee B. Global Prevalence of Post COVID-19 Condition or Long COVID: A Meta-Analysis and Systematic Review. The Journal of Infectious Diseases. Published online April 16, 2022. doi:10.1093/infdis/jiac136

^{xi} WHO 2021 Coronavirus update 54: Update on clinical long-term effects of COVID-19 the latest on the covid-19 global situation & long-term sequelae

^{xii} WHO Regional Director for Europe Dr Hans Henri P. Kluge, 19 July 2022 Statement, Rapidly escalating COVID-19 cases amid reduced virus surveillance forecasts a challenging autumn and winter in the WHO European Region <https://www.who.int/europe/news/item/19-07-2022-rapidly-escalating-covid-19-cases-amid-reduced-virus-surveillance-forecasts-a-challenging-autumn-and-winter-in-the-who-european-region> Last accessed: 19/08/22

^{xiii} World Health Organization, Interim statement on COVID-19 vaccination for children. August 2022. Available at: <https://www.who.int/news/item/11-08-2022-interim-statement-on-covid-19-vaccination-for-children> . Accessed: August 2022

^{xiv} IFS (2022) Long Covid and the Labour market <https://ifs.org.uk/publications/long-covid-and-labour-market>

^{xv} Chan Sui Ko A, Candellier A, Mercier M, Joseph C, Schmit JL, Lanoix JP, Andrejak C. Number of initial symptoms is more related to long COVID-19 than acute severity of infection: a prospective cohort of hospitalized patients. Int J Infect Dis. 2022 May;118:220-223. doi: 10.1016/j.ijid.2022.03.006. Epub 2022 Mar 5. PMID: 35257903; PMCID: PMC8896858.

^{xvi} GAVI - <https://www.gavi.org/vaccineswork/silent-pandemic-how-drug-resistant-superbugs-risk-becoming-worlds-number-one-killer>

^{xvii} World Health Organisation. (2019), 2019 Antibacterial Agents in Clinical Development – An analysis of the antibacterial clinical development pipeline

^{xviii} Antimicrobial resistance collaborators (2022) Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis, The Lancet, January 20,2022

^{xix} World Health Organisation (2019): No time to wait: Securing the future from drug resistant infections report

^{xx} Superbugs to trigger our next global financial crisis, OUTBREAK consortium (2020)

^{xxi} Shawview Consulting chart and analysis. Data sources: Department of Health and Aged Care, PBS Expenditure and Prescriptions Report, various years;

<https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions>, Commonwealth of Australia, Final Budget Outcome, various years, www.budget.gov.au

^{xxii} Shawview Consulting chart and analysis. Data sources: Department of Health and Aged Care, PBS Expenditure and Prescriptions Report, various years;

<https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/pbs-expenditure-and-prescriptions>, Commonwealth of Australia, Final Budget Outcome, various years, www.budget.gov.au

^{xxiii} Medicines Australia Submission to the PBAC on the Base Case Discount Rate, Biointelect and Shawview Consulting (2022) - <https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2022/02/Medicines-Australia-submission-to-PBAC-Discount-Rate-Submission-January-2022.pdf>