

Pfizer Australia is one of Australia's leading providers of prescription medicines. We manufacture medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives.

We began operations in Australia in 1956 with six colleagues at our Australian headquarters in West Ryde. Today, Pfizer Australia employs more than 1500 colleagues in a variety of fields including science, medical, regulatory affairs, manufacturing, sales and marketing, health economics, research and development.

Every day our people work with the sole purpose of ensuring that Australians can access new and innovative medicines that are being used to treat some of the most feared conditions of our time. We are proud of the active role we play in Australia's health system and the wider contribution we make as an innovator, employer and manufacturer.

Pfizer Australia is a member of Medicines Australia (MA), the peak body representing innovative pharmaceutical companies in Australia. Pfizer Australia was involved in the preparation of MA's detailed response to this consultation, and we fully support their recommendations to Government.

The health technology assessment and PBS reimbursement system in Australia administered by the PBAC is at a pinch point. We are on the cusp of a new range of therapies 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. Consumers are becoming 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.

Australia's Long-Term National Health Plan has set the ambitious target of delivering the 'world's best healthcare system'.¹ If this is to be achieved, then there needs to be reform to the PBS.

*"A strong economy, a strong budget.... is what guarantees the essential services you rely on."
Prime Minister Scott Morrison (2019)*

As part of the 2019-20 Federal Budget, Prime Minister Scott Morrison and Health Minister Greg Hunt announced the PBS listing of BAVENCIO®, a treatment for a rare and aggressive skin cancer, metastatic merkel cell carcinoma. The listing of BAVENCIO on the Pharmaceutical Benefits Scheme (PBS) helped improve the lives of more than 3000 Australians diagnosed with this aggressive life-threatening condition each year.

BAVENCIO was just one of a number of medicines announced as part of the 2019-20 Federal Budget, part of a \$331 million investment over five years from 2018-19 for new PBS listings.

Announcing the listing of BAVENCIO Prime Minister Morrison stated that the listing of medicines is an essential Government service and a 'sign of a strong economy'. Pfizer would agree and commends the Government for its continued commitment to list all medicines recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the PBS.

Since its inception in 1948 the Pharmaceutical Benefits Scheme (PBS) has provided Australian patients with access to affordable and high quality, safe and effective medicines, when they need them. It has been a staple of the National Medicines Policy that has established a strong working relationship between the Federal Government and the medicines industry and delivered world class health outcomes for Australians.

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Prior to the 2019 Federal election the Government committed to a review of the National Medicines Policy. There had been a growing push to review the overarching policy for some time. The policy is more than 20 years old and the review was recognition that the way medicines are developed and delivered today, is vastly different to twenty years ago and will change exponentially in the next twenty.

The same can also be said for how we assess the value of medicines. The PBS has proved a robust model for the consideration of health interventions, and it has delivered great value to Government. However, challenges threaten the status quo - an aging population, increasing incidence of chronic conditions and a proliferation of innovative therapies will increase pressure on the system.

Our priority should be to ensure that patients have access to affordable treatments. The coming year will bring careful consideration of how our health technology assessment and PBS reimbursement processes can facilitate this. A first step should be removing the cost-offset policy.

While we have more to do, this will allow our medicines sector to invest with confidence in the treatments of tomorrow and ensure we can bring our patients the best medicines of today.

Removing cost-offset policies from the PBS

A large number of today's innovative medicines are targeted and personalised that treat highly complex conditions, such as cancer and rare diseases. Specialty medicines can provide great value in some of the hardest-to-treat diseases and may offer a more targeted treatment, meaning they may be more effective or better tolerated than other available options. They are developed under the strictest clinical guidelines and this research and development presents significant risk and cost to the manufacturer.

Market access systems around the world are currently grappling with the challenge of assessing the value of these medicines. Innovation in precision medicine promises substantial benefits and it will change the way in which some health services are delivered and evaluated. As biomarker discovery accelerates and artificial intelligence-based technologies emerge, refinements to the methods and processes of evidence assessments will help to adapt and maintain the objective of investing in healthcare that is value for money. ⁱⁱ

In Australia this is no different. Increasingly manufacturers are facing challenges and uncertainty in the listing of new medicines on the PBS. These challenges are compounded by an "offset" policy that requires every new dollar spent on new medicines to be counterbalanced by an equivalent offset, determined in advance, from within the existing health budget.

There is no question that the implementation of a cost-offset policy is delivering savings across the PBS. It is, however, evident that we are approaching a point where the continued downward pressure on pricing, combined with the need to continually find space within the existing budget for new listings will limit timely access to medicines for the patients that need them.

Looking ahead, we must have the right systems in place to deliver the best healthcare outcomes in this rapidly changing environment. Removal of the requirement to fund new medicines via cost-offsets is an important first step in this regard and will deliver growth to the PBS budget through the listing of new medicines, the value of which will still be appropriately evaluated by the PBAC.

Pfizer recognises that the PBAC may continue to play an important role in the assessment of medicines into the future, however, its processes need sensible reform in order to deliver timely access to Australian patients to the next generation of medical breakthroughs.

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Sustainable access to medicines across the supply chain

There is no question that reform is required to enable our healthcare system to cater for the growing number of precision medicines coming in the years ahead. There is also a need to ensure that the system is appropriately valuing high volume, low cost medicines, many of which are critical life-saving medicines used as last line in the hospital setting.

One example of this is the current market for anti-infective medicines in Australia. Simplified Price Disclosure has continued downward pressure on the price of these medicines and is creating issues with sustainability of supply. Hospital procurement practices have also continued to drive down prices, particularly for older, established medicines. This has contributed to increasingly frequent supply problems. In some circumstances, a supplier may be unable to continue supply or may choose to exit the Australian market for one or more medicines. This places increased pressure on the remaining suppliers, as they work to address the ensuing market shortfall. This is particularly difficult because supply issues typically emerge at very short notice.

Manufacturing anti-infective medicines is a complex process and it can take as long as six to 12 months, or even longer to meet increased market demands. In some cases, this has led to essential antibiotics not being available for Australian patients. Shortages can in turn, lead to protocol changes to higher grade antibiotics as their supply is more consistent. This increases the risk of anti-microbial resistance within these hospitals and depending on the significance of the market shortage can lead to an increased risk to patients across the country, as was seen in November 2016 when there was a critical shortage of several important anti-infective medicines due to suppliers vacating the market at short notice.

Pfizer has first-hand experience of this through our anti-infectives portfolio of medicines, but the issue also impacts critical oncological and mental health medicines. In some cases, the manufacturing and distribution costs associated with these medicines is more than the price secured through a hospital tender. This is not sustainable and if manufacturers of our size and scale are experiencing issues then there is a real risk of market failure if more and more manufacturers find it is not feasible to continue to produce these medicines, which could lead to critical shortages and a real threat for patients.

In considering reform to the PBS for innovative medicines Pfizer proposes that there also needs to be consideration of value-based pricing for sustainable access to all PBS medicines.

A stronger medicines industry means a stronger economy

Australia has entered its 28th year of consecutive annual economic growth. Healthcare is an important contributor to Australia's GDP and has shown stability and predictability over the last two decades. As the Australian economy continues to ride the wave of the resources sector, continuing to diversify to a services-based economy will provide economic stability into the future.

Australia's economy is dominated by the services sector, which accounts for more than 75 per cent of real gross value added (GVA). Healthcare and social assistance is the third largest contributor of gross added value (7.9%), more than mining (6.4%), manufacturing (6.3%) and retail (4.8%). It is also a steadily growing sector demonstrating an average annual growth rate of 4.4% since 1991. ⁱⁱⁱ

The innovative pharmaceutical industry is an important cog in the healthcare system. It contributes to the health and wealth of Australia by providing new treatments to save and improve people's lives and keeping people in the workforce. The industry further contributes to the Australian economy by undertaking business, investing in local

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manufacturing, partnering with research organisations and sharing research throughout the wider ecosystem. In 2016 it was estimated that the pharmaceutical industry contributed more than \$8.9 billion to the Australian economy and supported more than 22,900 jobs.^{iv}

Pfizer is proud to be part of an industry that has helped treat, cure and eradicate life-threatening diseases. We play an active role across the Australian healthcare spectrum working with patient organisations and government for the benefit of each patient. Our workforce of more than 1500 colleagues supports an additional 10,500 jobs and we contribute \$2.5 billion to the Australian economy each year.

Pfizer's economic footprint also includes:

- A significant investment in Australian-based clinical trials. In 2018 Pfizer invested more than \$40 million in more than 50 clinical trials at more than 280 sites across the country, helping to stimulate Australia's biotech sector and providing critical access to potentially revolutionary new treatments for Australian patients.^v
- Our vaccines protected more than 330,000 people from diseases including meningococcal and pneumococcal disease and in 2018 we helped over 1480 patients across Australia and New Zealand living with rare diseases like acromegaly, Gaucher disease and growth hormone related disorders.
- Pfizer employs 1,000 colleagues across our three manufacturing sites -Perth (Bentley), Melbourne (Mulgrave) and Adelaide (Thebarton). Our plants manufacture for both the domestic and international markets – exporting to more than 60 markets worldwide.
- Every year more than a billion doses of therapeutic goods are manufactured by Pfizer in Australia for distribution within domestic or international markets. This includes more than 15 million vials of critical medicines that are exported to the United States and Canada each year.

Conclusion

The coming year will be critical for the future of the medicines industry in Australia. It is clear there is a shared commitment from Government and industry to deliver the latest medicines to Australian patients at an affordable price.

However, there are growing challenges that threaten this goal. The current cost-offset policy risks constraining the future of the PBS and making it increasingly difficult for manufacturers to bring forward new and innovative medicines. Increased costs of manufacturing and supply are also impacting the sustainable supply of medicines to patients and this needs to be addressed with value-based pricing.

Australia's healthcare system delivers world leading outcomes and does many things well. Common-sense reform can address some of the current obstacles to affordable access and lay a foundation that can help deliver the 'world's best system' in years to come.

ⁱ Australia's Long Term National Health Plan (August 2019) - <https://www.health.gov.au/resources/publications/australias-long-term-national-health-plan>

ⁱⁱ The Future of Precision Medicine: Potential Impacts for Health Technology Assessment (December 2018) - Love-Koh, Peel et al. *PharmacoEconomics*, Volume 36, Issue 12, pp 1439–1451,

ⁱⁱⁱ Why Australia: Benchmark Report 2019 - Australian Trade and Investment Commission <https://www.austrade.gov.au/International/Invest/Resources/Benchmark-Report>

^{iv} The economic contribution of the innovative pharmaceutical industry to Australia - PwC Consulting, 2017. Report commissioned by Medicines Australia.

^v Pfizer Database, December 31, 2018. Clinical Trial Protocols include non-investigational and investigational studies