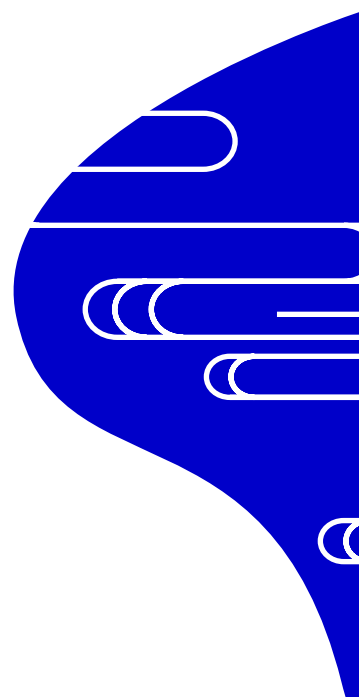




# Breakthrough Nation

*A 10-point plan for how the life sciences  
sector can drive Australia's health and wealth*



# A message from our Managing Director

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

Pfizer was founded in New York in 1849 and has been at the centre of medical research and innovation for close to two centuries. We are very proud to be celebrating the 175<sup>th</sup> anniversary of the company in 2024 and look forward to continuing to develop breakthroughs that change patients' lives for many years to come.

Pfizer has had operations in Australia since 1956. We have around 1,000 employees in Australia and operate across commercial sites in Sydney and Melbourne, and a manufacturing facility in Melbourne that exports to more than 60 countries worldwide.

We are proud to be making a significant investment into our Melbourne manufacturing site. We have committed over \$150 million for upgrades, which will allow us to conduct highly specialised manufacturing in Australia for export to the world.

This report calls on the government to issue a Life Sciences Vision that would underpin work towards making Australia more competitive in the global fight to attract life sciences investment. The report sets out priority areas and key recommendations that we believe will be key to setting Australia up for future success.

## Anne Harris

Managing Director,  
Pfizer Australia & New Zealand



# Executive summary

As a leader and longstanding player in the life sciences sector, both in Australia and globally, we know the important role life sciences play not only in our health systems but in our economies and societies. We believe the life sciences sector can play an even greater role in contributing to Australia's health and wealth.

This report calls on the government to issue a Life Sciences Vision, like that issued by the UK government in 2021,<sup>1</sup> that establishes priorities for the sector and reinforces and strengthens ongoing work to attract investment into research, clinical trials and manufacturing in Australia.

We think the life sciences sector should be central to our national growth as we diversify beyond reliance on primary industries. Australia's high quality research institutions and strong public hospital system make it a good candidate for further investment. But in the absence of clear vision from government outlining priorities, Australia has not been a focus for life sciences investment.

As a precursor to any government statement on the role of the life sciences sector in Australia, Pfizer has identified **five key themes** and corresponding recommendations that we believe are at the centre of addressing the challenges faced across our industry and our health system:



1 *Deliver a prevention revolution to prepare for future threats*

2 *Ensure no patient is left behind*

3 *Accelerate equitable access to new medicines and vaccines*

4 *Make Australia an attractive destination for international investments in life sciences*

5 *Unite across the life sciences sector to deliver a net zero health system*

These themes relate not just to Pfizer or the pharmaceutical sector but are common across the life sciences industry and underpin Australia's ongoing health and wealth as a nation. As we face increasing and compounding health and fiscal challenges, this report sets out the big ideas that will ground the work of the life sciences sector over the coming years.

# Introduction

The life sciences sector is central to Australia's future. Innovative medicines and vaccines fundamentally underpin our national health and wealth as they keep people well and productive. For example, early and broad COVID-19 vaccination in Australia was estimated to have contributed \$181 billion to the Australian economy<sup>ii</sup> and avoided many thousands of COVID-related deaths.<sup>iii</sup>

We find ourselves in a new era for our health system, COVID-19 emergency measures have been removed but our health systems continue to experience increased pressure. Budgets are stretched and must go further to respond to additional illness caused by COVID-19 as well our aging population.

As our population ages, hospital admissions for complex chronic conditions increase. We also face workforce and productivity challenges across our health systems. The time is nigh for reforms that see us work more efficiently, making investments in prevention that have a multiplier effect and acting early to avoid expensive, late-stage interventions.

The life sciences sector is poised to provide solutions (both medicines and vaccines) that support our national health and wealth. We are living in a period of unparalleled medical breakthroughs and innovations. New therapies are emerging for conditions previously considered untreatable. In order for Australians to enjoy the benefit of this innovation we must ensure Australians get timely and equitable access to the newest and best innovations.



It is important that the life sciences sector shows leadership in combatting the key challenges of our time. We recognise that climate change is one of the defining issues requiring collective action to mitigate the potential risks, including the potential for adverse impacts on human health. As such, we support Government efforts to reduce greenhouse gas emissions, and see opportunities for collaboration as Pfizer Inc works to achieve our own Net Zero by 2040 goals.

We also have an important role in supporting the creation and retention of highly skilled jobs in research and manufacturing. While we don't have a complete picture of jobs created across the life sciences industry, Medicines Australia member companies alone employ 22,900 Australians and contribute \$8.9 billion to the economy.<sup>iv</sup> The clinical trials sector employs 7,700 Australians and generates \$1.6 billion for the economy.<sup>v</sup> Domestic manufacturing of medicines, including Pfizer's plant in Melbourne which employs around 500 Australians, plays an important role in keeping critical technical skills in Australia.

With greater focus on the sector from government and investors, further gains can be made. Australia has the potential to be a centre of life sciences innovation, building on our high-quality educational institutions and public health system. This will not only lead to the creation of jobs and wealth in Australia but also Australians gaining faster access to the innovative medicines and vaccines that are essential to our health and wellbeing as a nation.



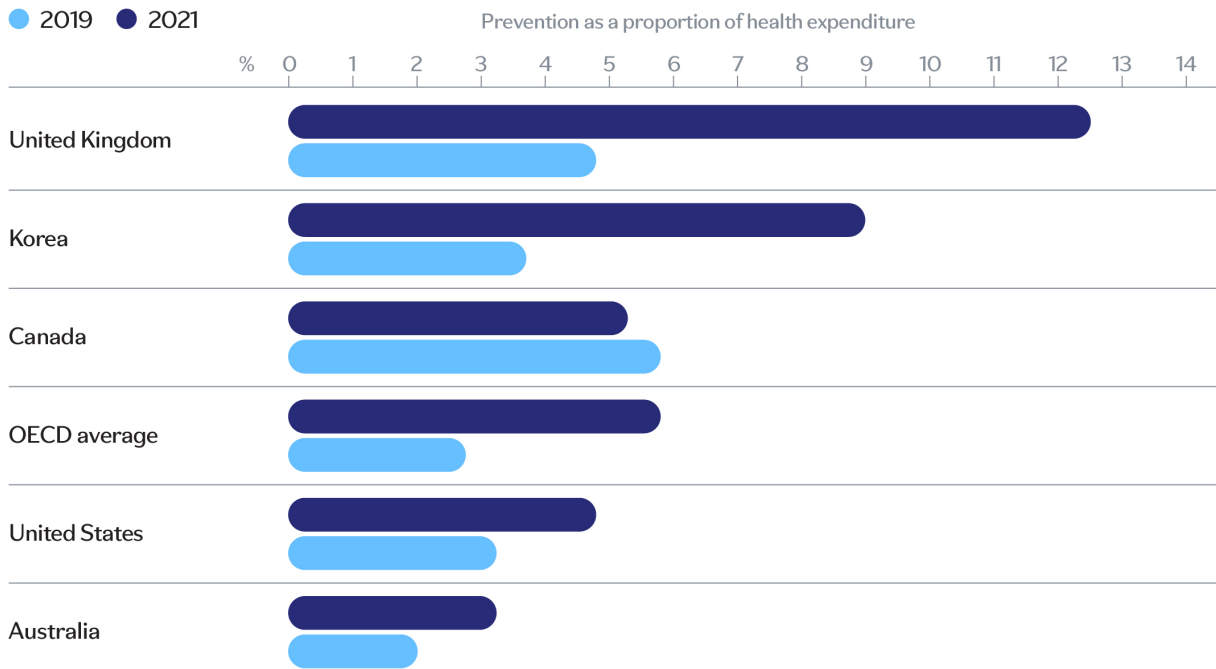
# 1

# Deliver a prevention revolution to prepare for future threats

The challenges around funding and resourcing our health system are well known. Running hospitals is costing more and will continue to cost more as our population grows and ages. We are seeing critical skills shortages across hospitals, as well as across primary care including general practice, and health budgets are stretched across the country.

We need to revolutionise the way we think about, and deliver, healthcare in Australia. We know treating a person once they are sick, especially when they require hospitalisation, is much more expensive than keeping them well. But our health system doesn't prioritise prevention.

In 2020-21 Australia allocated just 3% of total health expenditure to public health and prevention, up from 2% in 2018-19<sup>vi</sup>. This placed Australia 29<sup>th</sup> out of the 36 advanced economies for per capita expenditure on preventative health, substantially behind countries with similar health systems to ours, including Canada (5%), Korea (9%) and the UK (12%) which have made substantial investments in cost effective interventions like vaccination and screening (see Figure 1).<sup>vii</sup>



**Figure 1. Share of spending on prevention in current health expenditure, 2019 and 2021 (or nearest year)**

Source: OECD Health Statistics 2023

We need to restructure our health system to account for the economic and workforce challenges that come with an aging population. A key factor in achieving this will be to fundamentally change health funding and place new emphasis on programs that keep Australians well at all stages of life.

### Recommendation 1

Act on the recommendation of the National Preventative Health Strategy and set a 5% minimum target for investment in preventative health by 2030.

### Recommendation 2

Create targets for adult vaccination in line with those for childhood vaccination, and implement new funding arrangements for adult vaccination that link funding to uptake as well as transparent reporting of vaccine uptake for all age groups.

### Recommendation 3

Implement a novel funding arrangement for antimicrobials that delinks the revenue of the antimicrobial from volume sold to tackle antimicrobial resistance (AMR).

## Workforce and productivity

Keeping Australians healthy is good for the economy. In 2017, the Productivity Commission conservatively estimated that the GDP could be increased by \$4 billion per year if the health of people in fair or poor health was improved.<sup>ix</sup> Similarly, economic loss due to early retirement from ill health was \$45.3 billion in 2017; a figure, which is expected to increase to \$53.4 billion by 2025.<sup>x</sup>



Economic modelling clearly shows that we should be shifting the way we fund health to prioritise prevention. If action were taken to address the wider determinants of health, it is estimated that:

- **170,000** more Australians could enter the workforce, generating **\$8 billion** in extra earnings
- **annual savings of \$4 billion** from reduced demand for welfare payments
- **60,000** fewer people would need to be admitted to hospital annually resulting in savings of **\$2.3 billion** in hospital expenditure
- **5.5 million** fewer Medicare services would be needed each year, resulting in annual savings of **\$273 million**
- **5.3 million** fewer Pharmaceutical Benefit Scheme prescriptions would need to be filled each year, resulting in annual savings of **\$184.5 million** each year<sup>xi</sup>

Creation of a target for a minimum spend of 5% of the health budget on prevention could lead to savings across the health system as preventative health interventions including vaccination and screening programs can prevent illness and allow early intervention, reducing hospital admissions, length of hospital stay, use of prescription medicines, and deaths.

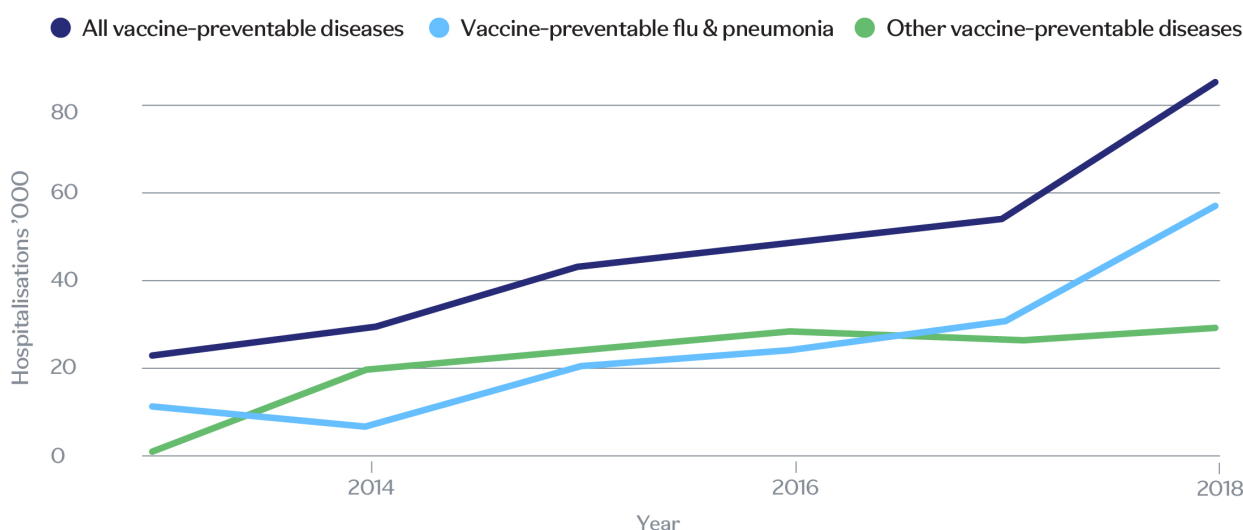
## Vaccination

Vaccination is a safe, highly effective and cost-efficient preventative health intervention. Vaccines protect against viruses and bacteria that cause diseases that can be life threatening or fatal.

Childhood vaccination rates in Australia are very high. In recent years they have consistently remained around 95% which is the level required to achieve herd immunity. Conversely, vaccination rates for older adults are poor. For example, the Grattan Institute found only 27% of older Australians are up to date with their COVID vaccination, less than half of Australians in their 70s are vaccinated for shingles and only one in five is vaccinated for pneumococcal disease.<sup>xii</sup>

Failure to achieve high vaccine uptake in older adults leads to avoidable illness, hospitalisation and death. This is a missed opportunity. The Government has funded and made available potentially lifesaving vaccines, but low uptake means people continue to fall ill, require hospitalisation and die of vaccine-preventable illnesses, which has flow on effects across our health system and economy.

Vaccine-preventable diseases cause tens of thousands of potentially preventable hospitalisations each year



**Figure 2. Hospitalisation for vaccine-preventable diseases in Australia<sup>xiii</sup>**

Source Grattan analysis of AIHW (2020a, National Data Table)

A higher vaccination rate yields savings across the health system. In 2015-16, vaccine-preventable conditions cost the hospital sector \$616.7 million.<sup>xiv</sup> Figure 2 shows the increasing rate of avoidable hospitalisation associated with vaccine preventable diseases. While comprehensive data are not yet available; the advent of COVID-19 as an additional source of vaccine-preventable hospitalisations imposes a further, and avoidable burden, on our stretched hospitals.

A 2024 report from the Office of Health Economics, found that adult vaccination programs can return up to 19 times their initial investment when the full spectrum of economic and societal benefits is valued. The return is equivalent to up to USD \$4,637 in net monetary benefits to society per individual full vaccination course.<sup>xv</sup>



There is a broad consensus around the importance of increasing vaccine rates in Australian adults. The Grattan Institute recommended a new *National Vaccines Partnership Agreement* that sets national goals for adult vaccination.<sup>xvi</sup> Similarly, the Australian Immunisation Coalition recommended targets for adult vaccination coverage as key performance indicators in the *National Partnership Agreement on Essential Vaccines* and the next *National Immunisation Strategy*.<sup>xvii</sup>

An investment that creates targets for adult vaccination in line with those for childhood vaccination, and includes implementation of new funding arrangements for adult vaccination that link funding to uptake, as well as transparent reporting of vaccine uptake will be important to reducing the potential impact of vaccine-preventable illnesses, hospitalisations

## Pandemic preparedness

As we saw during the COVID-19 pandemic, vaccination was an essential part of getting out of the emergency phase and continues to be important in preventing serious illness, hospitalisation and death. It is essential that we learn the lessons of COVID-19 and get our pandemic preparedness measures right, so we are best prepared to weather the next pandemic threat.

Modelling has shown, the probability of a pandemic with similar impact to COVID-19 is around 2% in any given year.<sup>xviii</sup> Societal trends that increase connectedness between countries, like globalisation and travel, can further accelerate the spread of high-risk pathogens.

The CSIRO 'Strengthening Australia's Pandemic Preparedness' report recommended greater investment in early stage science as well as vaccines research and manufacturing, diagnostics and antivirals<sup>xix</sup> and the Halton review into Australia's purchasing and procurement of COVID-19 vaccines and treatments recommended a portfolio approach to ensure we don't put all our eggs in one basket.<sup>xx</sup>

## Antimicrobial resistance

Antimicrobial resistance (AMR) is a growing health challenge that has been described as 'the silent pandemic' and is considered by the World Health Organisation to be a top 10 area of public health concern for the 21<sup>st</sup> century.<sup>xxi</sup> Failure to act on AMR could mean routine surgeries like caesarean sections or joint replacements are no longer possible because of the risk of contracting an untreatable infection.

Without intervention, it is estimated that by 2050, 10,000 Australians will die each year from drug resistant infections.<sup>xxii</sup> A recent study in the journal *Infectious Diseases and Therapy* found reducing antimicrobial resistance for just three bacterial pathogens could save Australia at least \$10 million in hospitalisation costs and provide economic benefit of more than \$400 million over 10 years.<sup>xxiii</sup>

**“Despite the huge societal costs of antimicrobial resistance and urgent need for antimicrobials, there is no viable market for new antibiotics in Australia.”<sup>xxiv</sup>**

**- *New Frontier Report***

The first line of defence in the battle against AMR is vaccination. Vaccines are designed as a critical tool in the prevention of serious, life-threatening infections and contribute to the responsible use of anti-infective drugs because with fewer infections in the community, less prescribing is required to treat those who become ill.

It is estimated that over half a million deaths associated with AMR globally could be prevented using vaccines.<sup>xxv</sup> For instance, global vaccination against *S. pneumoniae* alone, at 2019 coverage levels, averted approximately 44,000 deaths associated with AMR in 2019.<sup>xxvi</sup>



With increasing vaccine coverage for bacterial infections, we will require less prescribing of antimicrobials. However, not all infections can be prevented by vaccination, therefore we also require urgent action to incentivise development of new antimicrobials to ensure we have a pipeline that allows us to stay ahead of resistance.

Antimicrobials are different to other medicines as they need to be used sparingly to avoid accelerating the development of resistance against these medicines. This leads to poor returns on research and development (R&D), as company revenue is linked to the limited number of prescriptions dispensed. Similarly, when novel antimicrobials are cost-matched to low-cost generics, our systems fail to appropriately price the value of the innovation, making it yet more difficult for companies to justify their R&D investments and maintain sustainable operations in this space.

## Spotlight 1

### Six-part strategy to address AMR

*Pfizer takes its role in combatting the threat of AMR very seriously. As one of the original signatories of the 2016 Davos Declaration calling for collective action to create a sustainable and predictable market for antibiotics, Pfizer has joined other companies in endorsing the Industry Roadmap for Progress on Combating Antimicrobial Resistance.<sup>xxvii</sup> Globally, Pfizer endorses a six-part strategy to help address AMR.*

#### 1. Antimicrobial stewardship

Antimicrobial stewardship practices can help to reduce the spread of antimicrobial resistance by applying greater oversight of appropriate antibiotic usage to enable more rational and judicious prescribing practices. Pfizer also believes that effective stewardship of antibiotics includes responsible manufacturing practices.

#### 2. Manufacturing

Pfizer is committed to ensuring that the manufacture, use, and disposal of products, including antibiotics, do not adversely affect human health or the environment.

#### 3. Regional and global surveillance

Regional and global surveillance of antibiotic resistance patterns are an important tool to assess both the nature and the scope of the problems as well as the effectiveness of our efforts to combat them.

#### 4. Vaccination

Vaccines are designed as a significant tool to help prevent serious, life-threatening infections and therefore contribute to the responsible use of anti-infective drugs; efforts are needed across stakeholders to strengthen vaccine access and utilisation.

#### 5. Supportive regulatory frameworks

As part of the global effort to incentivise new antibiotic and vaccine R&D, there is a need to develop a tiered regulatory framework that allows either disease-based or pathogen-based label indications and promotes the most appropriate use of new agents.

#### 6. Incentives and new business models

Renewed focus on antimicrobial R&D efforts and support of the development of additional antimicrobials and vaccines will be critical in broadening the tools available to address antimicrobial resistance. Pfizer believes that the spread and scope of R&D can be incentivised through a mix of novel business models and economic incentives.

There is a clear need for new funding approaches to respond to the broken market for anti-microbials. The New Frontier Report recommended implementation of a pilot scheme for value-based payments for new antimicrobial drugs.<sup>xxviii</sup> The CSIRO *Curbing Antimicrobial Resistance* report recommended fit-for-purpose funding models, and financial incentives for antimicrobials.<sup>xxix</sup> Similarly, the Australian AMR Network's *Fighting Superbugs* report recommended implementation of a funding model that delinks financial returns from their volume of utilisation and recognises their inherent public health value, based on the scheme successfully implemented in the UK.<sup>xxx</sup>

We believe it is essential that Australia joins the UK and others in showing leadership in responding to the growing threat of AMR by creating a funding regime that de-links revenue from volume sold and instead bases revenue on the value of the anti-infective to our public health system. A fund for novel anti-infectives should be established in this term of government.

# 2

## Ensure no patient is left behind

Health equity across our population is essential. Australia can only achieve the productivity and economic benefits of a prevention revolution if they are felt across all parts of our society. A fair society is a productive society.

This means we need to ensure we are addressing the social determinants of health that impact segments of our community and ensure treatments and support are available for all patients, regardless of how rare their condition or what part of society they come from.

### Recommendation 4

**Create new fit-for-purpose and adequately resourced Health Technology Assessment pathways for rare disease therapies and for listing therapies on the Life Saving Drugs Program.**

### Social determinants of health

Where you live has a significant impact on your health outcomes. The 28% of Australia's population who live in rural or remote areas have an increased mortality rate of up to 1.5 times compared to their metropolitan counterparts, with the mortality rate increasing with remoteness.<sup>xxx1</sup> People living in very remote areas are hospitalised at almost twice the rate of those living in major cities.<sup>xxxii</sup>

These indicators are even worse for Aboriginal and Torres Strait Islander Australians where there is an overall life expectancy gap of 8.1 years for women and 8.8 years for men.<sup>xxxiii</sup> Around one-third (34%) of the health gap was due to social determinants, nearly one-fifth (19%) was due to 'health risk factors' and the remaining health gap (of around 47%) includes differences in access to appropriate health services.<sup>xxxiv</sup>

The social determinants of health are highlighted in Indigenous populations that suffer diseases not seen in other parts of the population. Trachoma, rheumatic heart disease and otitis media are significantly more prevalent in Indigenous communities and are associated with social determinants of health including poor quality housing and inadequate sanitation.

Work is being done to better utilise technology to improve access to the health system for those living in remote areas, and to provide culturally appropriate care for First Nations peoples and Australians born overseas. But there remains significant work in addressing inequity.

## Spotlight 2

### *Pfizer's contribution to First Nations peoples' health*

As a purpose driven organisation, committed to working through the Reconciliation Action Plan framework, we are playing our part in seeking to improve health outcomes for First Nations people.

We are proud to work in partnership with the National Aboriginal Community Controlled Health Organisations including through sponsorship of a post-graduate scholarship for a First Nations pharmacist and co-design of patient resources.

We are similarly proud to work with MALPA Young Doctors health promotion program for First Nations children and sponsor 35 Smith Family Learning for Life Scholarships.

We work with our partners to deliver training to healthcare professionals involved in delivering care to Indigenous communities including supporting over 700 health workers through training on vaccination education and work with Cairns Hospital to train healthcare professionals in treating rheumatic heart disease while maintaining patient involvement to support treatment adherence.

We strongly believe commitment to the process of reconciliation is essential to working with First Nations people to advance health equity. This will continue to guide our focus into the future.

## Rare Disease

Addressing the social determinants of health is only part of the solution to addressing inequality in health outcomes. We must also ensure our health responses are calibrated to support Australians with all the health conditions that occur across our population, not just common ones.

 **Approximately 8% of Australia's population live with a rare disease<sup>xxxv</sup> and 30% of Australians impacted by rare disease experience diagnostic delays of more than five years.<sup>xxxvi</sup>**

**We need to operate differently to ensure people impacted by rare disease have equitable access to the therapies they need. The standard approach to considering medicines for inclusion on the PBS relies on data from large numbers of patients, which is not available for rare disease treatment, and doesn't adequately consider the clinical benefit or broader societal impacts of making the treatment available.**

People who suffer from rare diseases struggle to get a diagnosis which means they aren't receiving appropriate treatment, but even when a diagnosis is achieved, rare disease patients in Australia often can't access the treatments they need. Rare disease treatments, like novel antimicrobials, are often not prioritised for research and development (R&D) because commercial incentives are weak with small patient cohorts and governments unwilling to pay for new therapies.

The Life Saving Drugs Program (LSDP) is an important mechanism for providing access to therapies for people impacted by ultrarare diseases. However, the process of listing a therapy on the LSDP is unnecessarily cumbersome. To list a therapy on the LSDP, the medicine must first fail the cost effectiveness test of traditional HTA methods to then be eligible to make an application for the LSDP.

The New Frontier's Report observed this problem and recommended the 'assessment process for the LSDP be streamlined and delays in access to treatments reduced by ensuring that a sponsor only need lodge one application for one Health Technology Assessment pathway'.<sup>xxxvii</sup> Faster patient access would be achieved with the creation of a fit-for-purpose and adequately funded HTA pathway for listings on the LSDP.



# 3

## Accelerate equitable access to new medicines and vaccines

Innovative medicines and vaccines make a tremendous contribution to Australia's health and wealth. Not only do they keep people well, but when people become sick, their availability means patients spend less time in hospital and have better overall survival rates.

Independent research found that diseases for which there were larger increases in the number of PBS medicines tended to have smaller subsequent growth in premature mortality (before ages 85, 75, and 65).<sup>xxxviii</sup> Diseases for which there was larger growth in the number of PBS medicines also tended to have smaller growth in the number of hospital days 2–10 years later.<sup>xxxix</sup> Simply put, innovative medicines on the PBS saves lives, and reduce hospital admissions and length of stays.

In Australia, we aren't experiencing the full benefit of innovative medicines and vaccines because our Health Technology Assessment (HTA) policies, processes and methods create inbuilt delay and mean Australian patients wait too long to access the medicines and vaccines they need.

### Recommendation 5

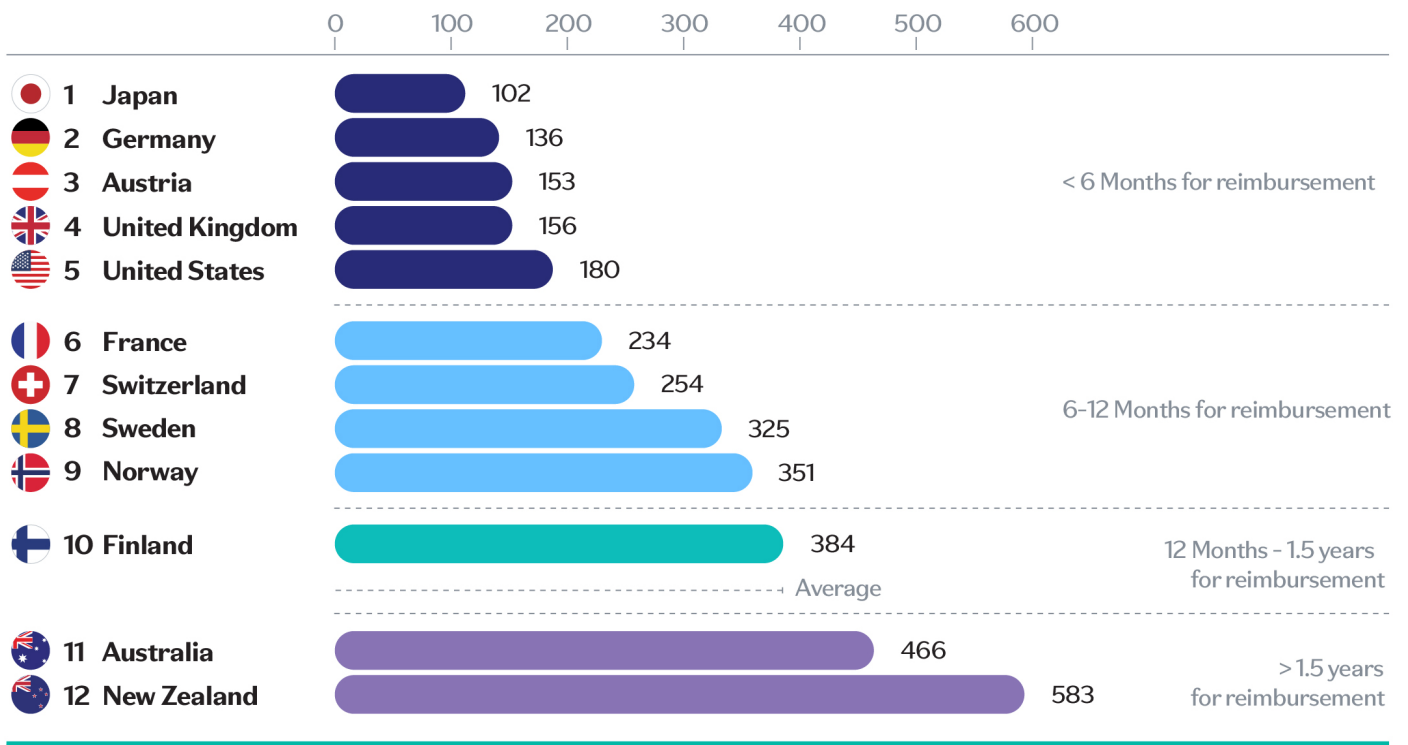
**Working in alignment with the shared goals in the Strategic Agreement (2022–27), the government should undertake bold reform of HTA policies, methods and processes to ensure medicines are funded on the PBS within 60 days of TGA registration.**

### Recommendation 6

**Prioritise expenditure on innovative medicines as a proportion of health spending to ensure our health system prioritises securing access to cutting-edge treatments for Australians.**

Australian patients wait too long to access innovative medicines and vaccines. In fact, it takes on average 466 days for a new medicine to go from TGA registration to PBS listing.<sup>xl</sup> This is almost 100 days slower than the OECD average and more than 300 days slower than Japan, Germany or the UK.<sup>xli</sup> This delay negatively impacts patient outcomes and our economy as treatment is delayed.

We must transform our funding models so Australians have access to innovative medicines and vaccines as soon as possible, with broad access, at prices that value innovation and are affordable for government and patients.



**Figure 3. Comparing days from registration to reimbursement in OECD countries<sup>x1</sup>**

Source Medicines Australia, 2022, ‘Medicines Matter: Australia’s access to medicines 2016-2021’, pg. 9

Our pathways are slow, cumbersome and unpredictable. This leads to sponsors making multiple resubmissions over years, delaying access. On average, companies make 1.7 submissions per new therapy,<sup>xliii</sup> with only 17% of new therapies reimbursed within six months of registration.<sup>xliv</sup> Less than half (44%) of new medicines registered in Australia between 2016-2021 went on to be reimbursed, compared with 96% in Japan, 84% in Germany, 80% in the UK and 62% in France.<sup>xlv</sup>

We should have a streamlined pathway for low-budget impact submissions. This would achieve faster patient access, and free up government and industry resources for more complex submissions.

The existing Managed Access Program is not fit-for-purpose. We should substantially reform or replace it to ensure we have a program equipped to provide early equitable patient access to new technologies before the final terms of PBS listing are agreed where there is clinical need, limited treatment options and substantial clinical benefit.

A new value framework is required to ensure value considerations are explicit, transparent and broad, and shift the conversation from medicines being about cost to being an investment in health. Cost-effectiveness decisions should place more emphasis on patient experience, equity, wellbeing, impact on the broader health system, and other elements like carer burden. This framework is not something we set and forget. It must be subject to continual review and improvement to ensure our systems and policies keep pace with innovation and the full impact of the disease on the community.



Our inflexible approach is letting patients down and causing avoidable illness. We have seen our one-size-fits-all approach fail to adequately value novel antimicrobials and rare disease treatments. Similarly, vaccines generate significant savings across our health systems and benefits across our economy by keeping people well and in the workforce. However, our evaluation system undervalues them with high discount rates, under-accounting for benefits accrued over multiple budget cycles, exclusion of broader societal benefits, and limited acceptance of real-world evidence.



This means it is harder to get vaccines funded in Australia which undermines efforts to prioritise preventative health.

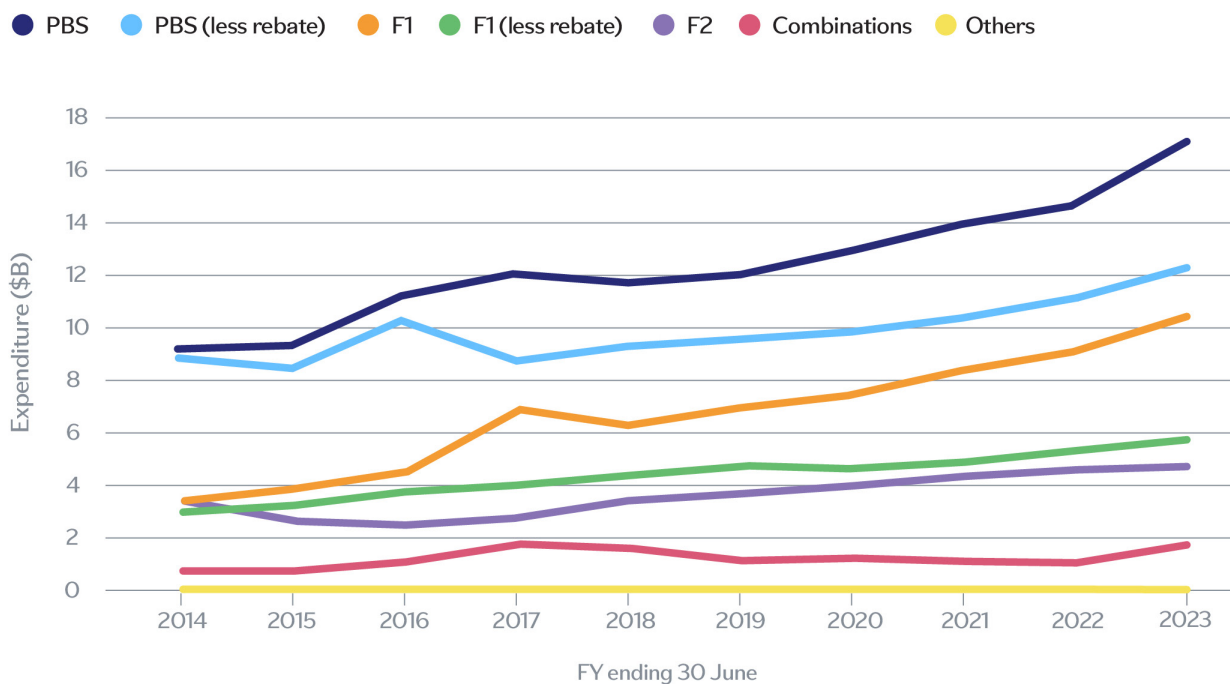
In the New Frontier Report the House of Representatives Health Committee recommended numerous changes to the way we perform HTA in Australia. In the government's response, the HTA Review was consistently identified as the appropriate avenue for considering these changes.

It is essential that the recommendations of the New Frontier Report, together with the hundreds of inputs received to the HTA Review to improve access are acted upon. Australian patients are waiting too long and sometimes missing out on treatment altogether.

A commitment to having medicines funded on the PBS within 60 days of TGA listing will provide the policy grounding to ensure the required process and methods changes are made to ensure faster medicines access for Australian patients.

Implementing these changes will keep Australians alive, healthy and in the workforce, with substantial productivity gains and economic returns, but will require an initial investment. Over the last decade, while the total PBS spend has increased, the proportion of the PBS that funds innovative medicines has seen minimal growth (see Figure 4). This means, as a proportion of GDP, the government's expenditure on innovative medicines is going backwards (see Figure 5).

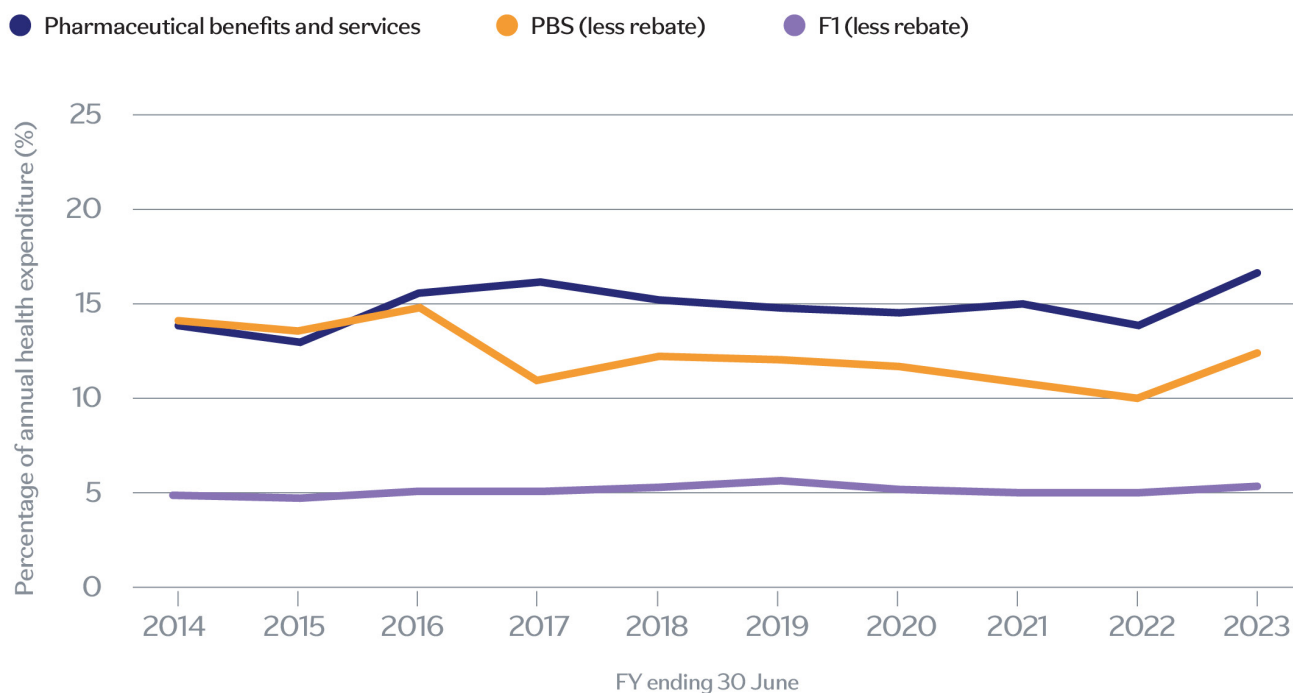
### Annual nominal PBS expenditure breakdown



**Figure 4. PBS Spend by purpose over time**

Source: Shawview Consulting chart and analysis. Data: PBS Expenditure and Prescriptions Reports 2014-2023.

### Annual nominal health portfolio expenditure breakdown as a proportion of total health expenditure



**Figure 5. PBS (less rebate) and F1 (less rebate) as a proportion of health expenditure**

Source: Shawview Consulting chart and analysis. Data: Department of Health and Aged Care, PBS Expenditure and Prescriptions Report, various years, Commonwealth of Australia, Final Budget Outcome, various years.

# 4

## Make Australia an attractive destination for international investment in life sciences

The government should be commended for announcements in the 2024 budget including the introduction of the Clinical Trial One-Stop-Shop which will mean a substantial reduction in red tape when running multi-site clinical trials across Australian jurisdictions.

Though importantly, in order to increase Australia's competitiveness when it comes to attracting investment into research and development (R&D), clinical trials and manufacturing, we need not only a clear vision from the government but also establishment of a supportive policy ecosystem.

### **Recommendation 7**

**Issue a clear policy statement that identifies objectives, priorities and key opportunities to allow Australia to retain and attract significant life sciences investment.**

### **Recommendation 8**

**Implement a patent notification arrangement, as intended under the Australia-US Free Trade Agreement, where patent holders are notified of potentially infringing applications for registration upon application.**

### **Recommendation 9**

**Introduce a target for government investment in research and development as a proportion of GDP of at least the OECD average.**

## Investment in R&D in Australia

Australia has the potential to be a world leader in science and innovation. We have world class research institutions and public hospitals for clinical trials as well as a substantial investment from government through the National Health and Medical Research Council, the Medical Research Future Fund and the National Reconstruction Fund. However, improved coordination is necessary to translate our many advantages into breakthroughs for patients and outcomes for business.

A Life Sciences Vision, like that issued by the UK Government in 2021,<sup>xlvi</sup> would be an opportunity for the Australian Government to outline priorities and opportunities in the Australian life sciences sector, to encourage focused collaboration across industry and academia towards priority areas and create the policy landscape required to see Australia succeed in attracting additional investment.

## Patent notification

A strong intellectual property system is an essential part of a vibrant R&D ecosystem. Without the ability to protect and commercialise ideas there is little incentive to invest in innovation.

Australia's legal system is robust and respected. But the absence of patent notification arrangements creates in-built delay and unpredictability. In the Australia-US Free Trade Agreement, Australia agreed to make necessary arrangements for 'notification to the patent owner if another party submits a medicine for marketing approval during the term of an existing patent' though action has not been taken to bring such an arrangement into existence.

Instead of notifying the patent holder when a potentially infringing generic or biosimilar product commences the registration process, the patent holder only becomes aware of the potential infringement by carefully monitoring new additions to the Australian Register of Therapeutic Goods. The patent holder is then left with an emergency injunction as their only recourse to prevent launch while litigation is pending, which is costly for parties and time consuming for the courts.

A patent notification system would allow negotiation, and if necessary, litigation, to occur while the registration process is ongoing rather than once it has concluded. It would make our patent system more predictable without impacting competition or access to medicines.



## Maintaining open supply chains

Pfizer's strategy for manufacturing is based on a network of global sites to leverage economies of scale for distribution and export to global markets to enable sustainable, reliable patient access to medicines. Throughout Pfizer's 175-year history, we've developed the industry's most agile manufacturing infrastructure and made significant investments to get crucial medicines to patients faster – from penicillin during World War II to the COVID-19 vaccine – always with the greatest focus on safety, quality, and compliance.



The COVID-19 pandemic highlighted the importance of resilient and sustainable supply chains. We utilise our global supply chain and work with supply chain partners at each stage of the value chain of our products to drive efficiencies and optimisation across our entire network.

Global supply chains spread the risk of supply chain challenges across the global value chain unlike domestic production which centralises the supply chain risk at Australia's border. When production is centralised in a single country, a supply chain interruption could mean a facility that relied on imports for domestic production could no longer operate. Global supply chains where ingredients are sourced from multiple locations and there are multiple translation points spread the risk of possible supply interruptions across the whole supply chain instead of focusing it at a single point (such as Australia's border).



**Global supply chains were critical to Pfizer's ability to produce and supply vaccines at the unprecedented scale and speed seen during the COVID-19 pandemic. Pfizer's first in class supply chain and logistics arrangements meant we delivered on time and at scale for the COVID-19 vaccine which involves the use of over 280 materials sourced from 86 suppliers in 19 different countries.**

## Spotlight 3

### Pfizer's Melbourne manufacturing site

Our manufacturing site in Melbourne is an important part of our global supply model. The plant employs around 500 people and manufactures oncology products and antimicrobials that are exported to over 60 countries.

We are in the process of investing over \$150 million upgrading the plant. The upgrades include productivity enhancements like robotics and ensure the site continues to operate at the cutting edge of highly specialised manufacturing.

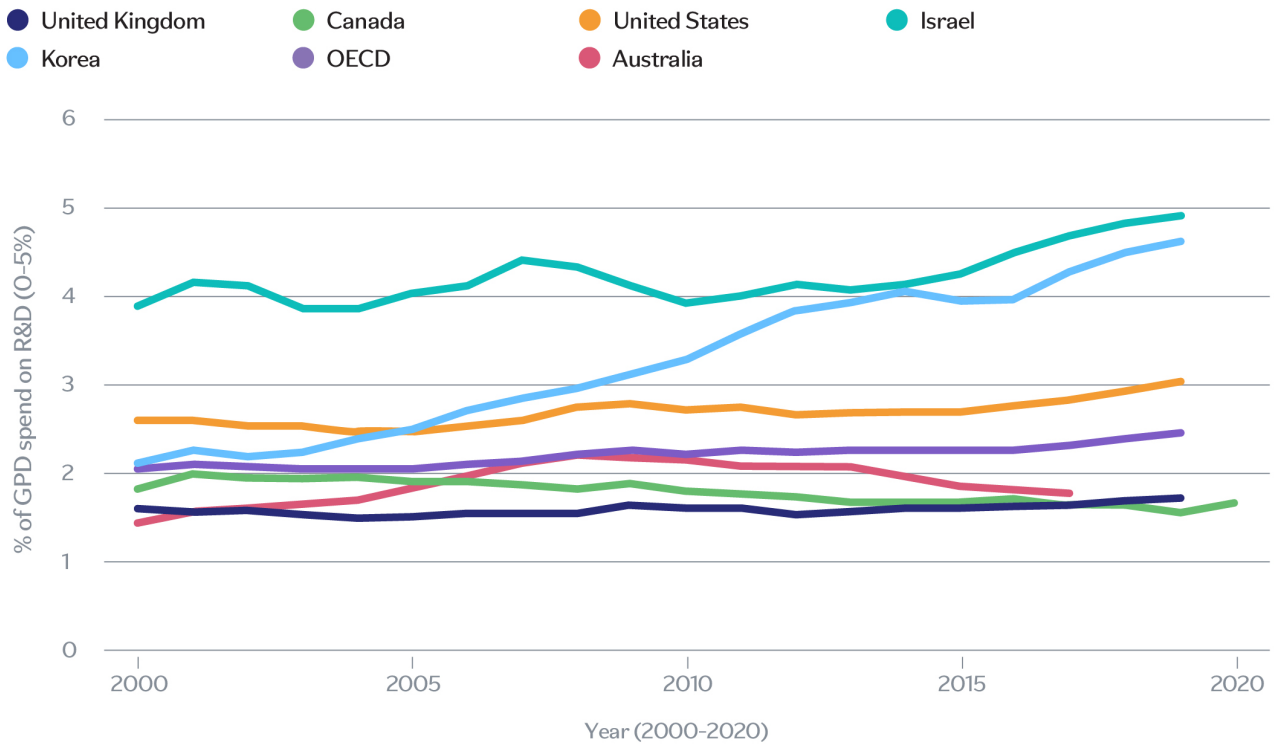
Pfizer Melbourne has over 100 years of heritage in sterile medicines manufacturing. The business, that is now Pfizer Melbourne, was first established by compounding pharmacist David Bull in 1915. Our current Melbourne site was acquired by David Bull Laboratories in 1973. The business changed hands over the years and was finally acquired by Pfizer in 2015.



### R&D investment

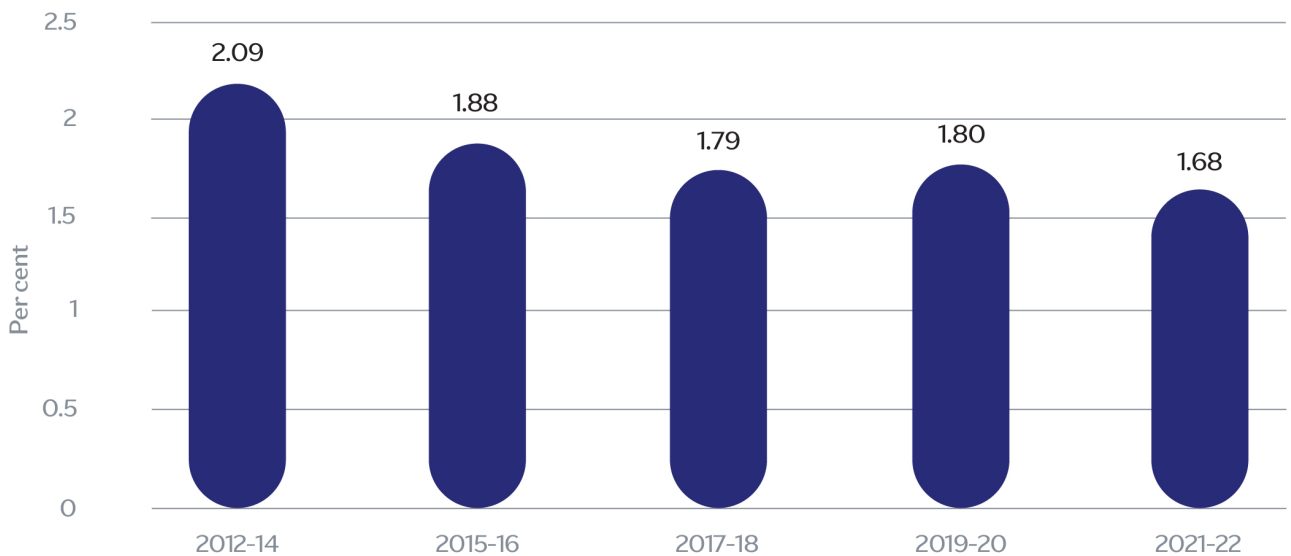
Government schemes that incentivise research and manufacturing investments in Australia, such as the R&D tax offset, are important and should be expanded. Investment in R&D has an important multiplier effect whereby innovation in Australia is nurtured, which in turn fosters the creation of employment and economic growth.

Based on 2021 data, Australia is ranked 21<sup>st</sup> in the OECD for investments in R&D as a proportion of GDP, spending just 1.68% which lags the OECD average of 2.7% and is substantially behind Israel at 5.6%, Korea at 4.9% or the US at 3.5% (see Figure 6).<sup>xlviii</sup> Australia has also decreased its investment in R&D as a percentage of GDP over the last decade which is a concerning trend (see Figure 7).<sup>xlix</sup>



**Figure 6. Total R&D spend by a percentage of GDP, 2000-2020<sup>1</sup>**

Source: OECD data, Gross domestic spending on R&D.



**Figure 7. Government R&D spend over time**

Source: Shawview Consulting chart and analysis. Data: ABS Research and Experimental Development, Businesses, Australia, 2021-22.

The combination of increased government focus and direction of the life sciences industry through a life sciences vision and increased investment in initiatives that support R&D through creation of a target for government investment of at least the OECD average are important initiatives that will assist in making Australia more competitive in attracting investments into early-stage research, clinical trials and manufacturing.

# 5

## Unite across the life sciences sector to deliver a net zero health system

Climate change is a key challenge. As our climate warms, there are wide ranging impacts on our health.<sup>ii</sup> Future pandemics and public health crises are likely to emerge as habitats are disrupted and we experience increasing severity and frequency of natural disasters. Consequently, we need to prepare our health system to manage related health impacts.

### Recommendation 10

**Set a net zero target for the health system to ensure all parts of the health system are working towards Australia's net zero commitment**

Australia's net zero by 2050 commitment is an important benchmark that will guide industry and our health system alike. The carbon footprint associated with the Australian health system in 2014-15 was estimated to represent 7% of Australia's total emissions.<sup>iii</sup> Pharmaceuticals contributed 19% of healthcare emissions in that year.<sup>iii</sup>

To achieve the net zero by 2050 target, we believe substantial ambition is required at all stages of the medicines value chain. Pfizer Inc is working to mitigate the effects of climate change on the environment and on human health, including through our commitment to achieving net zero across our value chain by 2040.

We are proud to be leading thinking globally on reducing greenhouse gas emissions across pharmaceutical value chains and intend to make energy and other efficiency upgrades at our manufacturing sites around the world, including at our Melbourne site.

Our efforts alone, however, will not create the level of action needed to mitigate these potential impacts. We recognise the urgent need for action by all sectors, public and private, and will continue to partner with others to address climate change across our value chain.

The UK determined that its National Health Service would work towards achieving net zero, with changes being made across models of care, hospitals and supply chains.<sup>iv</sup> Similarly, the U.S. Department of Health and Human Services (HHS) climate pledge calls on stakeholders across the U.S. healthcare system to reduce greenhouse gas emissions and build a more climate resilient healthcare infrastructure. Pfizer Inc, as one of the original signatories, committed to reduce greenhouse gas emissions, publicly report our progress, and develop a climate resiliency plan.

We believe more needs to be done across government and industry to unite around work towards a net zero and low waste health system for Australians.



## Spotlight 4

### *Pfizer Inc's net zero goals*

Pfizer Inc has a strong record in addressing our environmental impact. In June 2022, we accelerated our plans to decarbonise, setting a bold target of achieving the voluntary Science Based Target Initiative's Net Zero Standard across our value chain by 2040. This means Pfizer Inc aims to achieve a 95% reduction in company (Scope 1 and 2) GHG emissions and a 90% reduction in value chain (Scope 3) emissions by 2040, compared to our 2019 baseline.

The Science Based Target Initiative's voluntary corporate standard, encourages organisations to reduce their company emissions by 95% and value chain emissions by 90% by 2050.

As part of our Net Zero ambition, Pfizer Inc is also working to accelerate change across our supply chain, driving 64% of our suppliers of goods and services by spend to also set science-based greenhouse gas emission reduction goals by 2025.

The creation of a net zero standard across the Australian health system would encourage all players across the health system to collaborate and share experiences towards achieving the shared goal of substantial reductions in health sector emissions.



# Table of recommendations

*A 10-point plan for how the life sciences sector can drive Australia's health and wealth.*

Deliver a prevention revolution to prepare for future threats

- 1 Act on the recommendation of the National Preventative Health Strategy and set a 5% minimum target for investment in preventative health by 2030.
- 2 Create targets for adult vaccination in line with those for childhood vaccination, and implement new funding arrangements for adult vaccination that link funding to uptake as well as transparent reporting of vaccine uptake for all age groups.
- 3 Implement a novel funding arrangement for antimicrobials that delinks the revenue of the antimicrobial from volume sold to tackle antimicrobial resistance (AMR).

Ensure no patient is left behind

- 4 Create a new fit-for-purpose and adequately resourced Health Technology Assessment pathway for rare disease therapies and for listing new therapies on the Life Saving Drugs Program.

Transforming the PBS to accelerate equitable access to new medicines and vaccines

- 5 Working in alignment with the shared goals in the Strategic Agreement, the government should undertake bold reform of HTA policies, methods and processes to ensure medicines are funded on the PBS within 60 days of TGA registration.
- 6 Prioritise expenditure on innovative medicines as a proportion of health spending to ensure our health system prioritises securing access to cutting-edge treatments for Australians.

Make Australia an attractive destination for international investment in life sciences

- 7 Issue a clear policy statement that identifies objectives, priorities and key opportunities to allow Australia to retain and attract significant life sciences investment.
- 8 Implement a patent notification arrangement, as intended under the Australia-US Free Trade Agreement, where patent holders are notified of potentially infringing applications for registration upon application rather than upon registration.
- 9 Introduce a target for government investment in research and development as a proportion of GDP of at least the OECD average.

Unite across the life sciences sector to deliver a net zero health system

- 10 Set a net zero by 2040 target for the health system to ensure all parts of the health system are working towards Australia's net zero commitment.

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