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Pre-Budget Submissions
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Thank you for providing Pfizer Australia with the opportunity to contribute to the 2024 pre-budget submissions process.

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

Pfizer has had operations in Australia since 1956. Our Australian business operates across two commercial sites in Sydney and Melbourne, and a manufacturing facility in Melbourne that exports to more than 60 countries worldwide.

Pfizer commends the Government on the release of the Wellbeing Budget Statement in 2023 which recognised the importance of measuring and benchmarking a broader range of social and environmental factors and broadening the conversation about quality of life. Medicines and vaccines provide obvious benefits to the health of individuals – and, as the COVID years demonstrated, they also make a significant contribution to productivity and societal well-being.

Pfizer is pleased to take this opportunity to raise issues requiring urgent action in our health system including providing an ambitious response to the HTA Review, mainstreaming prevention in our approach to health, pandemic preparedness and clinical trial harmonisation.

Yours sincerely

Anne Harris
Managing Director

Ambitious response to the HTA review

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 listing on the PBS.[i] This is almost 100 days slower than the OECD average and more than 300 days slower than Japan, Germany and the UK. [ii] This delay does a disservice both to patient outcomes and to our economy.

It is essential that we update the way we decide what is eligible for inclusion on the PBS so Australians have access to the best available innovative medicines as soon as possible at prices that appropriately value the innovation and are affordable for government and patients.

Submissions to the HTA Policy and Methods Review have argued there is significant scope for reform. Eliminating redundancies and improving efficiency in the HTA processes is clearly needed, however, if this occurs without fundamentally reforming evaluation and decision criteria used to determine the way Australians get access to innovative medicines and vaccines, we will have missed an opportunity.

Our pathways are slow, cumbersome and unpredictable. This leads to sponsors making multiple submissions which delays patient access. On average, companies make 1.7 submissions per new therapy,[iii] with only 17% of new therapies reimbursed within six months of registration.[iv]

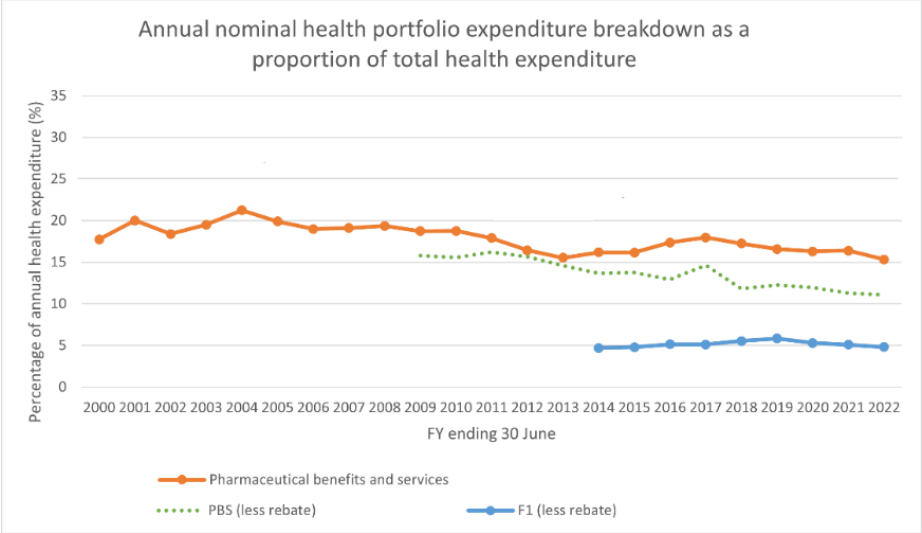
Similarly, the list of therapies that do not go on to be funded in Australia is substantially larger than in comparable countries. Less than half (44%) of new medicines registered in Australia between 2016-2021 went on to be reimbursed, compared with 96% in Japan, 84% in Germany, 80% in the UK and 62% in France.[v]

Australia lags other developed countries when it comes to accessing the most innovative medicines. The 2023 Global Access to Medicines Report found '[w]hile 85 percent of new medicines launched globally since 2012 are available in the United States, just 34 percent are available in Australia, with Australian patients waiting an average of 21 months from global first launch for the fewer medicines that do become available. Further, only 24 percent of new medicines are publicly reimbursed by the PBS, taking an average of 47 months from global first launch to PBS listing.'[vi]

A new value framework is required to ensure value considerations are explicit, transparent and broad and shift the conversation from cost to investment. Cost-effectiveness should be redefined to include patient experience, equity, wellbeing, innovation and other elements like carer burden. Importantly, this framework cannot be set and forget. It must be subject to continual review and improvement to ensure our systems and policies keep pace with innovation.

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. 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 increasingly informed and empowered to take control of their own health; their demand for access to the latest interventions will only increase in coming years.

When reviewing Government expenditure on the PBS since the start of the century it is evident from the impact of savings measures, combined with the growth in rebates that there has been minimal growth in expenditure on PBS. In fact, the PBS (after rebates) has been gradually falling as a share of health expenditure, and today it represents a smaller share of Commonwealth health expenditure than in 2000. [vii]



(*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)

As this figure shows, the industry has done substantial work with consecutive governments to deliver savings that can assist in funding new listings for innovative therapies. The Pharmaceutical Benefits and Services share of health expenditure (before adjusting for rebates) has declined from over 20% in 2004 to 15.3% 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 medicines (intended for single brand medicines) less rebates, has fallen below 5% of the total health spend.[viii]

Mainstreaming prevention in our approach to health

Prevention is an essential component of effective public health policies and systems. Whether targeted at individuals or populations, interventions aim to prevent disease incidence through programs of information, immunisation, screening or monitoring.

Only a small proportion of our health spend is on prevention. In 2018-19, prevention accounted for 2% of the health spend.[ix] This places us 20th in the world for per capita expenditure on preventative health, substantially behind comparable countries including Canada (6%) and the UK (5%).[x]

Pfizer notes that the National Preventive Health Strategy includes a goal to increase the preventative health spend to 5% by 2030.[xi] This is a positive ambition but must be achieved sooner than 2030 to achieve maximum economic and health benefits.[xii]

Australia's National Immunisation Program (NIP) provides a broad range of government funded vaccines from birth through to adulthood. Broad vaccination via the NIP has meant diseases such as rubella, tetanus, diphtheria, Hib and measles are extremely rare in Australia. Pfizer is proud to supply vaccines for pneumococcal disease and meningococcal disease to the NIP.

While childhood vaccination rates are strong, rates in other age groups lag significantly. 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 are vaccinated for pneumococcal disease.[xiii] While flu vaccination is higher than for other diseases,

with 63% of those over 65 vaccinated, it still falls short of the WHO target of 75% uptake for older people.[xiv] Failure to vaccinate key at risk populations including older Australians leads to avoidable illness, hospitalisation and death.

Vaccination is also an important measure in the fight against anti-microbial resistance. Vaccines contribute to the responsible use of anti-infective medicines because with fewer infections in the community, less prescribing is required to those who become ill. It is estimated that over half a million deaths associated with AMR globally could be prevented using vaccines.[xv]

Pfizer notes the 2021-22 Budget papers identified the need for vaccination targets for adolescents and adults as part of an effort to address the lag.[xvi] The National Preventive Health Strategy also highlights the importance of establishing a benchmark and targets for adults at increased risk of vaccine preventable diseases (such as pneumococcal, COVID, flu and RSV) due to age or underlying medical conditions.[xvii] Pfizer calls on the Government to bring targets for adult vaccination into line with those for childhood vaccination including implementation of new funding arrangements for adult vaccination that link funding to uptake as well as transparent reporting on vaccine uptake for all age groups.

Pharmacists have been shown to have a very significant role in safely administering vaccines. This is particularly relevant in regional and rural areas where there is even more limited access to GPs than in urban areas. The states and territories differ substantially in what vaccines can be administered by pharmacists leading to inequitable health outcomes depending on a person's state of residence.[xviii] In contrast, France permits pharmacists to administer all non-live vaccines with consistent application across the country. A harmonised national approach that adopts the best practice of vaccine access will help to deliver preventive benefits and improve patient equity across Australia.

Pandemic preparedness

As the world shifts away from the emergency response to COVID-19, the risk of another pandemic remains. The probability of a pandemic with similar impact to COVID-19 is around 2% in any given year[xix], meaning someone born in the year 2000 would have a 38% likelihood of having already experienced a pandemic by 2023. Societal trends that increase connectedness between countries, like globalisation and travel, can further accelerate the spread of high-risk pathogens. Recognising this, we must urgently act to achieve future pandemic health security.

The Government has placed increased importance on sovereign capability, however the nature of global supply chains means that simply creating local manufacturing capability does not guarantee rapid and easy access to products for domestic use. The Productivity Commission found '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.'[xx]

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. No country has end to end manufacturing for products as complex as COVID vaccines; vaccine manufacturing depends on a complex network of suppliers, competing for raw materials and equipment. Pfizer's COVID-19 vaccine, for example, consists of 280 components from more than 19 countries around the world.

The Halton Review of the procurement of Australia's COVID-19 vaccines observed that Australia's COVID-19 vaccine rollout was on par with other advanced countries.[xxi] However, the review strongly recommended that 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.'[xxii]

A mission-led approach to pandemic response is key. Pfizer is proud of the role it continues to play, along with State and Federal Governments and many other key stakeholders in a public-private partnership to turn the tide against COVID-19 and shelter the economy and the Australian community from an even more devastating fallout.

Improving Australia's response to the next pandemic will require proactive planning and broader, earlier availability of vaccines and treatments. The time for action is during non-pandemic times, enabling a more effective response in an emergency.

Novel reimbursement model for AMR

Antimicrobial resistance (AMR) occurs when bacteria, viruses, fungi and parasites evolve over time and no longer respond to current medicines making infections harder to treat and increasing the risk of disease spread, severe illness and death.[xxiii] Failure to act on AMR could mean routine surgeries like caesarean sections or joint replacements are no longer possible because of the high risk of contracting an untreatable infection.

Without preventative action, it is estimated that by 2050 AMR could lead to 10 million people dying every year and cost the global economy US$100 trillion.[xxiv] In Australia, the estimated annual impact of AMR on the economy by 2050 will be between A$142 billion and A$283 billion. [xxv] A recent study in the Journal Infectious Diseases and Therapy found reducing drug resistance for just three bacterial pathogens could, over 10 years, save Australia at least $10 million in hospitalisation costs and provide an economic benefit of more than $400 million.[xxvi]

New antimicrobials are urgently needed to treat drug-resistant infections and respond to the growing threat of AMR. Antibiotics are different to other medicines, as novel antibiotics need to be kept in reserve and used sparingly to avoid accelerating resistance. This leads to poor returns on R&D as income is linked to the number of units utilised during the limited period of patent validity. Similarly, when novel anti-infectives are cost-matched to older anti-infectives, many of which are 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 or to bring existing therapies to Australia given the uncompetitive reimbursement landscape.

Key countries are taking a leadership role and investing in novel reimbursement models to incentivise investments in novel anti-infectives. The UK government ran a successful pilot of a reimbursement model that de-linked revenue of an antimicrobial from the volume sold and based 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 approach helps to reduce the financial uncertainty in anti-microbial research and strengthens incentives to develop novel anti-biotics. Other countries including the US, Japan 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 support their position paper on the need for a novel reimbursement model to be trialled in Australia.

Establishment of a novel reimbursement model was also a key recommendation of the New Frontier's report from the House of Representatives inquiry into novel medicines and medical technologies.

Action on AMR is required now. The current budget measure expires this budget cycle. Having no measure in place to combat AMR would be an abdication of our responsibility as a leader in our region. A relatively modest investment, compared to Australia's contributions to global health entities such as GAVI or the Global Fund, would represent Australia's 'global fair share' in the fight against AMR. Such an investment would represent an important signal that Australia is taking a serious approach to this collective action problem.

Clinical trial harmonisation

To best harness Australia's potential as a centre for life sciences research and development we need a national one stop shop for clinical trials. Clinical trials make a substantial contribution to the Australian economy. They contributed almost $1.4 billion to the economy in 2019[xxvii] and employ at least 8,000 Australians.[xxviii] While government has committed to implementing this policy[xxix] it has not yet been funded. It is crucial that it is funded in this budget to avoid losing momentum and to secure Australia's future as a destination of choice for international clinical trials that can put patients at the forefront of potential new treatments. Commonwealth leadership in unifying the states' approaches to clinical trials will reinvigorate the Australian clinical trial sector and make Australia an attractive destination for this research activity in the future.

Currently, when a company includes Australian patients in a clinical trial, they must complete different governance and ethics approval processes in every state and territory.[xxx] This creates significant additional administrative burden and makes Australia a less attractive destination for the investment that comes with multi-site trials.

A national one stop shop, as outlined by Australian Commission on Safety and Quality in Healthcare, would mean a single set of rules would apply across the country making it simpler to undertake a multi-site trial in Australia.[xxxi] This is an important reform will make Australia more competitive in the global race to attract clinical trials.

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'[xxxii] 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.

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