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Productivity Inquiry
Productivity Commission
Locked Bag 2, Collins St East
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Dear Sir/Madam

RE: Productivity Commission – Five-year productivity inquiry

Thank you for providing Pfizer Australia with the opportunity to comment on the interim reports released as part of this inquiry.

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

The COVID-19 crisis has vividly illustrated the critical importance of life science research and innovation. When we look back on the impact of COVID in years to come, it will be a story of great loss and suffering, but also a story of resilience, of innovation, and of hope.

The collective effort of frontline health workers to support people in need, the work of our research sector to inform decision-makers on the disease and how it behaves, and the medicines industry coming together to accelerate efforts to find a vaccine - research that would ordinarily take years, that delivered viable options in a fraction of that time - has demonstrated compassion and firm resolve.

This extraordinary effort, in combination with the prompt action from Government and regulators has placed the nation in a sound position, and although the road back will be long, we remain hopeful that the medicines industry will play a critical role in leading the fight against COVID and the reinvigoration of the national economy.

Pfizer welcomes the Productivity Commission's five-year productivity inquiry and has been encouraged by recent comments from Commission Chair Professor Michael Brennan at the Rare Cancers CanForum recognising that a healthy nation leads to a healthy economy. A key lesson from the COVD-19 response must be that investment in the health of our nation is fundamental to our economic growth and stability which demonstrates the full value of medicines and vaccines. Traditionally, medicines and innovative medical devices have been seen by governments as a cost rather than an investment that can deliver additional economic benefits.

Pfizer's submission to the Commission focuses on interventions that can stimulate productivity, foreign direct investment and the diffusion of innovation as well as threats to Australia's productivity growth not detailed in the interim reports. Where possible Pfizer has aligned issues to the key themes articulated in the respective interim reports.

We would welcome the opportunity to discuss these issues further with the Commission in the future.

Yours sincerely,

Anne Harris
Managing Director, Pfizer Australia and New Zealand

ATTACHMENT 1: Productivity Commission – five year productivity inquiry

Interventions to stimulate productivity growth

(Relevant to interim paper 1)

Reform that will deliver timely access to medicines and vaccines

The Commission is right to recognise the benefit of medical interventions such as statins, anti-biotics, and vaccines in driving increases in quality and length of life. As well as recognising the role of innovation in driving productivity in Australia. However further work is needed to ensure Australians can access innovative medicines and vaccines in a timely manner.

The PBS has proved a robust model for the consideration of health interventions, and it has delivered great value to Government. However, in Pfizer's experience, Australia's reimbursement system is not keeping pace. The emergence of innovative, targeted therapies has tested the limits of our health technology assessment (HTA) process and created tension between payers, industry, clinicians and patients.

At the heart of these issues is a lack of consistency in decision making and the absence of clear measurable targets that demonstrate improvements in time to access of new medicines for patients. Pfizer would like to commend the Department of Health for recent reforms to address these issues, but we need to do more to ensure Australian patients do not fall behind the rest of the world. Attempts to address this have led to increasing layers of red tape. The result is a system that is increasingly complex, rigid and costly.

The volume of submissions made to the parliamentary inquiry into the approval process for novel medicines and medical technologies reinforces this. 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 failing patients.

The collective response to the pandemic and the decisions made to expedite approval of COVID vaccines, diagnostics and treatments demonstrates where there is a pressing need, there are solutions that can be found to improve access to medicines. We must keep moving forward and inquire how we can harness cutting-edge science and collaboration and apply this agility and innovation to address some of the most pressing health issues of our time - cancer, obesity, dementia, infectious disease and rare diseases.

Pfizer is a proud member of Medicines Australia which recently signed a new five-year Strategic Agreement with the Commonwealth that began 1 July 2022. Outlined in the agreement is an ambitious reform agenda that will strengthen the role of patients in Australia's HTA process and prepare Australia's HTA system for the next generation of treatments. It would be a huge, missed opportunity if at the end of this Strategic Agreement in 2027 we are citing the same inertia with the PBS and that this reform process didn't deliver meaningful change for Australian patients.

Intellectual property and patent protection need to be recognised as a bedrock of innovation

The paper states 'again, the distribution of gains can also be affected by institutional settings — such as legislation affecting how businesses compete (competition policy) and how much of the profits from innovation they can capture (this includes intellectual property rights legislation, and subsidies or taxes designed to alter relative prices, and therefore consumption).'

Pfizer views a strong and stable intellectual property (IP) system as critical to fostering pharmaceutical innovation, investment, productivity and competitiveness. A robust IP system underpins the development of innovative medicines and vaccines that enable people to live longer, healthier and more

productive lives.

A country's record on intellectual property is an influential factor when determining long-term investment decisions that drive local employment and patient access to breakthrough therapies. A strong IP system will also be critical to provide certainty for industry to be able to respond to future pandemics.

The incentives provided by the IP system enabled Pfizer to build the expertise and infrastructure that allowed us to quickly mobilise and devote the resources, technical knowledge and know-how required to combat the pandemic and has facilitated the advancement of cutting-edge technologies, such as mRNA vaccines. The IP system has also enabled an unprecedented number of collaborations between biopharmaceutical innovators and governments, universities and other research partners to speed up progress on finding solutions.

We appreciate the Commission's recognition of the critical role the IP system has played—and will continue to play—in ensuring the innovative biopharmaceutical industry can continue to innovate and collaborate in an effort to end this pandemic.

Regulatory data protection (RDP) is a separate mechanism that operates independently and in parallel to the patent system, protecting the disclosure and unfair commercial use of the clinical trial data submitted to regulators for the registration of a new medicine. A strong RDP regime can incentivise the development and local study of new medicines and drive timely patient access and is particularly important in situations where patents may not be available due to the nature of a new medicine, or in situations where the time needed to develop, test and secure approval for a medicine is so long that little or no patent term remains.

(Relevant to interim paper 3)

Access to novel antibiotics to reduce the threat of AMR and limit hospital stays

Paper three states that 'A large percentage of patients are being prescribed antibiotics for conditions for which there is no evidence of health benefits from antibiotic use such as non-infant acute tonsillitis (85 per cent of patients) and bronchitis (82 per cent of patients) (ACSQHC 2021a, pp. 79–80). There are also large numbers of preventable hospitalisations, with these varying considerably across locations, suggesting the scope for large-scale diffusion of best practice (ACSQHC 2021b).'

Pfizer agrees that antimicrobial stewardship is important, key element of which is investing in novel antibiotics to reduce the threat of antimicrobial resistance (AMR) in the community.

The World Health Organisation has said that the global pipeline of antimicrobials is insufficient to tackle the increasing challenge of antimicrobial resistance.[i] New antimicrobials are faced with very challenging access dynamics. In order 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. Last year, CSIRO Biosecurity Research Director Dr Paul de Barro stated "I don't think I'm exaggerating to say it's the biggest human health threat, bar none. COVID is not anywhere near the potential impact of AMR." [ii] A recently released study on the burden of AMR attributed 1.27 million deaths globally to bacterial AMR[iii] 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.[iv] In Australia, the estimated annual impact of AMR on the economy by 2050 will be between A$142 billion

and A$283 billion. [v] 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 the work they are undertaking to identify an appropriate economic model to introduce novel antimicrobials that suits the Australian context.

Continued investment in Australia's life sciences and recognition of the global value chain of medicines

Many development timelines were successfully accelerated during the COVID-19 pandemic, with multiple vaccines and therapeutics receiving conditional marketing authorisation in 2020/21.
Across multiple COVID-19 vaccines, pivotal trial timelines were reduced by 70% compared to a pre-COVID-19 benchmark. This required huge mobilisation of resources across industry, academia and governments/regulators, alongside new approaches to research and development whilst retaining high quality and safety standards, such as running multiple processes in parallel rather than in sequence.

A major focus of today's R&D ecosystem is understanding what can be learned from this experience and embedded elsewhere to continue to deliver important breakthroughs to patients. Importantly, this was only possible due to a long history of investment in research and development by industry, governments, and others, facilitated by incentives that support innovation across the research and development ecosystem.

The complexity of ecosystems required to advance research and development, product development, production and distribution of biopharmaceuticals, vaccines, and diagnostics, is such that they cannot be stood up from scratch in a real-time situation. They must already be in-place, fully operational, and proven well in advance of an emergent need.

(Relevant to interim paper 4)

Support for open trade vs sovereign capability

The paper 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.' Pfizer would recommend 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.

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.

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 needs to be a recognition that ingredients and components of the end product come from many sources and have multiple conversion points from raw material to finished product. Pfizer's COVID-19 vaccine for example consists of 280 components from more than 19 countries.

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. We are also incredibly proud that Pfizer's supply chain stood up to the challenges presented by COVID and we have to date been able to successfully deliver more than 3.8 billion doses of our COVID vaccine to more than 180 countries.

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.

Equitable access for vaccination

COVID-19 has highlighted the important role of both GP and community pharmacy services in providing access to vaccines. Many Australians have shown their willingness to utilise community pharmacy to receive their COVID-19 booster shots due to increased convenience. This is particularly relevant in regional and rural areas where access to a GP can often be difficult.

Whilst GP advice will always be a vital component of a patient's health journey, there is often a more frequent level of interaction between pharmacist and patient through the ongoing fulfillment of prescriptions, thereby providing a further option for discussion on available preventive health interventions like vaccination.

Varying approaches by states and territories to vaccine access leads to equity concerns for Australian patients based on their location. Excluding the COVID-19 vaccine, Queensland currently offers its residents access to nine separate vaccines through community pharmacy including for the prevention of life-threatening illnesses like Meningococcal and Pneumococcal diseases. In contrast Victoria, New South Wales and Western Australia pharmacies can provide access to five, and only three are available in all the other states and territories.

Pfizer supports calls for a harmonised national approach that adopts the best practice of vaccine access. This would help to deliver greater access to the important preventive benefits of vaccines to more Australians and thereby improve patient equity across the nation, whilst retaining the vital role of GPs as the key source of health guidance and advice.

Regulatory pragmatism and international collaboration

The paper mentions that in a 'number of industries, regulatory restrictions and other government interventions are themselves the cause for limited contestability or poor incentives for efficiency'.

One of the key aspects to the success story of the medicines supply chain during COVID-19 was the collaboration across the healthcare system that ensured we continued to deliver medicines to patients in a timely manner.

Maintaining the integrity of Pfizer's supply chain during the pandemic was not only resource intensive, but it required considerable engagement and advocacy with external stakeholders – to discuss the importance of maintaining open trade routes and to identify practical ideas that could see the removal of red-tape.

The Therapeutic Goods Administration deserves credit for recognising the need to have fast and efficient approval processes that made vaccines, diagnostics and treatments available to the community as quickly as possible.

It has been widely acknowledged that if we are to stay one step ahead of COVID variants and deliver the latest vaccines targeted to these variants then this regulatory pragmatism and international collaboration will need to become the norm. Ideally, an updated vaccine candidate needs to be in the market within 100 days.[vi]

Relevant to interim paper 5

Formal partnerships between tertiary sector and industry

Pfizer would recommend a more formal partnership between tertiary education and industry to ensure job readiness and appropriate skill development. This can reduce and remove obstacles to hiring local talent that still require significant on the job training to get up to speed, and reduce Australia's reliance on skilled migration to plug gaps in domestic capability and capacity,

Risks to Australia's productivity growth in the next five years:

The breadth and depth of the Commission's work, identifying levers through which to improve the diffusion and adoption of innovation by Australian companies is to be commended.

While each interim report acknowledges the impact of COVID-19 on the health and wealth of the nation there is an underlying presumption that the pandemic is over. That is not the case. Even if Australia was to move to an endemic COVID phase in the next few years there are ongoing risks such as the emergence of variants, declining rates of vaccination and ensuring access to antiviral treatments. If we fail on these fronts this could lead to increased case numbers, a rise in absenteeism and supply chain disruptions which threaten to undermine Australia's productivity. It is also important to embed the lessons learnt from the COVID-19 response to ensure Australia is better prepared to respond to any future viral threat that may emerge. If this were to occur, we know that acting fast is critical.

The critical importance of vaccines to Australia's long-term health security

Prevention is an essential component of an effective health system. Whether targeted at individuals or populations, interventions aim to enhance health status and maintain a state of low risk for diseases, disorders or conditions. That is, to prevent their occurrence through programs of information, immunisation, screening or monitoring. Yet only a small fraction of health spending is spent on prevention activities. On average, OECD countries allocate less than 3% of health spending on public health and prevention activities. Most countries fall within a band of 2% - 4%, which has remained stable over the long-term. Australia sits at just 1.34% which equates to approximately $89 per person.

Pfizer notes that the recently released National Preventive Health Strategy includes a goal to increase this investment to 5% of total health expenditure across Commonwealth, state and territory governments by 2030.[vii] This is promising; however, this level of under-investment must be redressed sooner than that to help drive Australia's economic recovery.

Australia has a strong National Immunisation Program providing a broad range of funded vaccines, free of charge, from birth through to adulthood. As a result of the NIP, diseases such as rubella, tetanus, diphtheria, Hib and measles are extremely rare in Australia. Maintaining and expanding our investment in immunisation will ensure broad protection of population health. This should include expanding the community's access to funded vaccines and maximising the uptake of vaccines for which funded access is already established.

While Australia has very high coverage rates for children, the rates are much lower for adolescents and adults. In the current COVID-19 context, maximising uptake for vaccine-preventable respiratory diseases can help to mitigate the annual burden of disease (increased mortality and morbidity and

healthcare costs) from influenza and pneumococcal disease, particularly in populations at greater risk of infection, such as those who are older and those with chronic diseases. In 2020, Australia reached its target of 95% immunisation of five-year-olds for the first time ever. Targets for adolescents and adults would be a first step in lifting the lagging coverage rates for these groups. The National Preventive Health Strategy also highlights the importance of establishing a benchmark and targets for adults at increased risk of vaccine preventable diseases due to age or underlying medical conditions and working towards meeting those targets. Establishing these targets will set a benchmark to work towards to address this issue in coming years.

In addition, expanding access to funded vaccines through the NIP would further improve the health and wellbeing of Australians. In the current context, expanding access to pneumococcal immunisation could prove important in reducing the overall burden of disease. Pneumococcal immunisation is currently recommended but unfunded for several vulnerable groups including adults with chronic respiratory disease such as COPD or severe asthma, chronic cardiac disease, diabetes and cancer undergoing chemotherapy or radiotherapy. These groups are also vulnerable to poorer outcomes from COVID-19, so preventative measures such as immunisation may help minimise the impact of the pandemic as COVID continues to evolve.

Improving health system resilience to manage another pandemic or viral threat

To improve health system resilience, Pfizer encourages governments to adopt their own evidence-based pandemic preparedness plans. Plans should help safeguard routine health services, ensure sustainable governance and financing structures for pandemic responses, and support scale-up of hospital capacity, including the health workforce and medical supplies. Plans should also include community engagement strategies that can build public understanding and confidence in vaccines, diagnostics, and therapeutics. These strategies should help drive health-seeking behaviors, mitigate vaccine and or drug mis- and disinformation, and incorporate transparent communications about the value of immunisation and other protective health measures.

Active, widespread public health surveillance is also necessary to mitigate future pandemics. For example, knowing which variants of the virus are most prevalent is important for vaccine and pharmaceutical product developers to be able to provide medical countermeasures that will provide the greatest level of protection against the virus.

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[i] World Health Organisation, (2019), 2019 Antibacterial Agents in Clinical Development – An analysis of the antibacterial clinical development pipeline

[ii] The Guardian Australia (2020): https://www.theguardian.com/world/2020/sep/10/superbugs-a-far-greater-risk-than-covid-in-pacific-scientist-warns

[iii] Antimicrobial resistance collaborators (2022) Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis , The Lancet, January 20,2022

[iv] World Health Organisation (2019): No time to wait: Securing the future from drug resistant infections report

[v] Superbugs to trigger our next global financial crisis, OUTBREAK consortium (2020)

[vi] https://100days.cepi.net/

[vii] National Preventive Health Strategy 2021–2030 - https://www.health.gov.au/sites/default/files/documents/2021/12/national-preventive-health-strategy-2021-2030_1.pdf