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NMP Review Secretariat
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Dear Committee,

RE: National Medicines Policy Review

Thank you for providing Pfizer Australia with the opportunity to comment on the review of the National Medicines Policy.

Pfizer Australia is one of the nation'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.

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

Pfizer has a proud history in Australia. We commenced operations here in 1956 with just six colleagues, and, more than 60 years later, we now have more than 1,400 colleagues working at two commercial sites and two manufacturing facilities across the country. Pfizer Australia is a member of Medicines Australia (MA), the peak body representing innovative pharmaceutical companies in Australia. Pfizer Australia was involved in the preparation of MA's detailed response to this consultation, and we fully support their recommendations to the Committee.

We are at a critical juncture for the future of the medicines industry in Australia. The collaboration and cooperation between industry and Government to arrest the impact of COVID-19 demonstrates a shared commitment to deliver the best available medicines and vaccines to Australian patients quickly and to take the necessary steps to get our nation back on its feet. More broadly, it has demonstrated that investment in the health of our nation is fundamental to our economic growth and stability which demonstrates the full value of medicines.

Australia's Long-Term National Health Plan has set the ambitious target of delivering the 'world's best healthcare system'. This review presents an opportunity to underscore this long-term goal with a progressive, world class medicines policy that recognises not only the challenges facing medicines access today but, in the years to come. Something all partners can uphold and improve upon as we work towards Australia remaining a 'first-wave' launch country.

Thank you again for the opportunity to contribute to this consultation. Pfizer Australia is available at any time to provide further information to the Committee as required.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Anne Harris'.

Anne Harris
Managing Director, Pfizer Australia and New Zealand

National Medicines Policy Review

Today and tomorrow's challenges

Many of today's innovative medicines are targeted, personalised and treat highly complex conditions, such as cancer and rare diseases. Specialty medicines can provide great value in some of the hardest-to-treat diseases and may offer a more targeted treatment, meaning they may be more effective or better tolerated than other available options. They are developed under the strictest clinical guidelines and this research and development presents significant risk and cost to the manufacturer. It can take on average, 10 to 15 years and cost \$2.6 billion to develop one new medicine, in addition to the cost of many failures. Only 12% of new molecular entities that enter clinical trials eventually receive U.S. Food and Drug Administration (FDA) approval.ⁱ

Payers around the world are currently grappling with the challenge of assessing the value of medicines and vaccines. Innovation in precision medicine promises substantial benefits and it will change the way in which some health services are delivered and evaluated. In Australia this is no different.

The challenges and opportunities associated with access to innovative medicines will only increase over the next decade. There will be considerable transformation in how health systems are designed, propelled by opportunities such as digital health, growing consumerism, and new partnerships and players in the pharmaceutical sector.

Personalised medicine is changing the way doctors treat complex diseases and is continuing to advance as scientists find new and innovative diagnostic and treatment options. A personalised medicine approach allows physicians to better understand disease drivers in each patient, and to select a treatment that increases the likelihood of a successful outcome. As the use of genomics becomes more wide-spread and cost effective, many more patients will have mapped their genome and will have a better understanding of their underlying risk to certain diseases.ⁱⁱ

Technology and its role in healthcare will increase. Wearables will not only become more prominent, but they will also become increasingly important in monitoring and managing a patient's wellness which could include diagnosis and adherence to medicationⁱⁱⁱ. The fragmentation of medical information across a variety of platforms will place a greater importance on addressing misinformation and promoting regulated, trusted sources of information.

Artificial intelligence and machine learning will also present opportunities to use data sets to understand when a person is at risk of developing a chronic disease, for example, and suggest preventive measures before they get worse. It will also aid in clinical trial design and diagnosis of rare conditions. The onus will be on governments, health systems and the private sector to ensure AI systems are fully interoperable and transparent and prevent bias and inequality.^{iv}

The medicines industry will expand and incorporate new partnerships and players. Large technology companies such as Dell, IBM, Google and Apple have already begun investing in healthcare, leveraging the large data sets and insights at their disposal. This will diversify the landscape and increase the number of partners to uphold the NMP. Precision medicines and targeted therapies will also require new manufacturing and distribution methods which will increase the scope and complexity of the supply chain.^v

It is difficult to encapsulate all these emerging issues and trends as part of the current NMP review but, as the last twenty years has demonstrated, ensuring this update of the NMP considers this evolving landscape will be a key challenge.

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A principled review of the National Medicines Policy

It is the right time to refine the National Medicines Policy (NMP). We are on the cusp of a new range of therapies that will require new thinking and adaptability to ensure that they are valued appropriately for manufacturers and government. Most importantly, we must ensure these medicines are available to the patients who need them, in a timely manner.

Consumers are no longer passive. They are informed and empowered to take control of their own health. The sheer volume of submissions and engagement in the recent House of Representatives inquiry into novel medicines and medical technologies should be heard loud and clear - patients want more involvement in decision making and policy that impacts them.

The NMP review needs to be future focused and aspirational. It needs to reflect the growing complexity of the medicines value chain and to recognise that Australia needs to benchmark against, and work with, other countries facing similar challenges to medicines access. Measures of success should be developed in consultation with the key partners so that we are all aware of the work we need to do to elevate the policy and strengthen its impact for patients. We hope that this review can serve as a catalyst for systemic change that will ensure that, in the years to come, we have a sustainable, thriving medicines industry that is making a marked difference to the economy and ensuring no patient is left behind.

Pfizer is supportive of the comprehensive work Medicines Australia (MA) has undertaken to produce a robust and comprehensive submission to this Review including their assessment of the updates required to the existing pillars of the NMP. Pfizer's submission will build on MA's recommendations and draw on our own experience as well as highlighting some emerging issues that if addressed can help future proof the revised NMP. We have included the following recommendations for the Expert Advisory Committee's consideration.

Pfizer's key recommendations

- 1) All partners to the NMP subscribe to becoming a partner in innovation.
- 2) The definition of medicines needs to be broad enough to include vaccines, transformative therapies and the next generation of medicines.
- 3) A revised NMP needs to consider incorporating Artificial Intelligence, connected devices and big data in the medicines value chain.
- 4) Quality use of medicines needs to recognise the importance of genomic profiling and precision medicine for the advanced detection and diagnosis of certain conditions.
- 5) The NMP needs to recognise the global context of medicines research, development manufacture and supply and the importance of strong and open global supply chains.
- 6) Consumers should play a pivotal role in the oversight and implementation of the NMP.
- 7) The NMP needs to reinforce that all partners play a critical role in disseminating trusted, reliable sources of medical information to address fragmentation and misinformation.
- 8) The NMP needs to expand the principle of equity to actively address existing health inequity.
- 9) A revised NMP should communicate to all partners how the principles and pillars will be applied and reviewed over time.
- 10) A forum for discussion between NMP partners, focused on collaboration and resolution of differences, in alignment with the vision for the NMP should be established.

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Terms of Reference 1: Evaluate the current NMP objectives and determine whether these should be modified, or additional objectives included. This includes consideration of the proposed principles to be included within the NMP.

The innovative pharmaceutical industry is an essential element of the healthcare system. It contributes to the health and wealth of Australia by providing new treatments to save and improve people's lives and keeping people in the workforce. The industry further contributes to the Australian economy by undertaking business, investing in local manufacturing, partnering with research organisations, and sharing research throughout the wider ecosystem. In 2016 it was estimated that the pharmaceutical industry contributed more than \$8.9 billion to the Australian economy and supported more than 22,900 jobs.^{vi}

Pfizer is proud to be part of an industry that helps prevent, treat, cure, and eradicate life-threatening diseases. We play an active role across the Australian healthcare spectrum working with patient organisations and government for the benefit of each patient. Our workforce of more than 1,400 colleagues supports an additional 10,500 jobs and we contribute \$2.5 billion to the Australian economy each year.^{vii}

All partners to the NMP should become 'partners in innovation'. This will be a resounding commitment to collaboration and partnership as well investment of time, resources, and money to foster advancement and growth, which will ensure the sector is globally competitive and attractive for investment. It is also about embracing an innovative mindset to how we measure success, assess new technology and adapt to change. If we focus on making wise and courageous choices of innovations, introducing them with quality improvement principles in mind, then our future healthcare systems will better serve patients.^{viii}

A similar approach has been taken as part of the UK's recently announced Life Sciences Vision which recognises that the sector is among the most valuable and strategically important in the UK, and critical to the nation's health, wealth, and resilience. It is recognition of the key role the sector will play in accelerating the development of new drugs, diagnostics, medtech and digital tools to bring life-changing innovations to patients more quickly.^{ix}

If all partners to the NMP subscribe to becoming a partner in innovation we can ensure Australia's medicines value chain is globally competitive, attractive to foreign investment, stimulates job growth and the economy and, most important of all, brings forth medicines that allow Australians to live longer, healthier more productive lives. Getting this right by establishing this within the NMP can ensure future reforms of the HTA process can apply the same lens and underpin Australia's ambition of creating the world's best healthcare system.

Recommendation: All partners to the NMP subscribe to becoming a partner in innovation.

Terms of reference 2: Defining medicines

Pfizer would argue that the last 18 months have demonstrated that the single, most important 'medicine' to the country and the world has been vaccines to address the threat of the COVID-19 pandemic. The current NMP does not mention vaccines however it does cite an objective of the policy is to '*provide incentives for preventive health and cost-effective care*'.^x

Preventive health measures will become increasingly important over the next decade. As the draft National Preventive Health Strategy states 'Australians in good health are better able to lead fulfilling and productive lives, participating fully in their community, in their education and/or in their employment. The benefits of this are experienced system-wide with decreased disease burden leading to a reduction in the pressures on our health system, and economic benefits demonstrated by an increase in Australia's gross domestic product (GDP)'.^{xi}

The response to the global pandemic has demonstrated that the health and well-being of our community will form the basis of our economic recovery. Prioritising preventive health measures, such as immunisation, will be key not only to this recovery but ensuring the long-term health of our nation. Prevention is an essential component of an effective health system.

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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. Australia has a strong National Immunisation Program providing a broad range of free vaccines from birth through to adulthood. As a result of the NIP, diseases such as rubella, tetanus, diphtheria, Hib, pneumococcal, meningococcal and measles are extremely rare in Australia.

There has also been considerable investment in genetic medicine, which has the potential to correct the underlying genetic defect in some rare diseases, and modify the course of the disease, rather than simply managing symptoms. Gene therapy holds promise for many of the millions of people worldwide living with rare, genetic diseases.

Unlike traditional medicines or therapies that typically require frequent administration and focus on managing symptoms and disease progression, gene therapy may offer long-term transformative benefits for people with rare genetic diseases, either potentially eliminating the need for ongoing therapies, or dramatically reducing the burden of daily disease management.^{xii}

Medicines Australia in their submission have included a broader definition of medicines for the review committee's consideration. Pfizer is supportive of this definition and of principally expanding the current definition of medicines to ensure the policy captures the advancements expected in health technology and treatment in the future.

Recommendation: The definition of medicines needs to be broad enough to include vaccines, transformative therapies and the next generation of medicines.

Terms of reference 3: Assess the NMP's utility in the context of rapidly evolving treatments options, population changes, interconnected relationships, and system-wide capacities.

New technologies — and consumers' high adoption rates — are driving behavioural change and becoming integral to all aspects of care. The evolution of technology in health supply chain and logistics is rapidly making the entire value chain more sophisticated and efficient.^{xiii}

Pfizer is using automation, artificial intelligence, and predictive analytics to modernise, streamline and simplify the development of medicines. Vast quantities of data can be collected and analysed with great precision, reducing the risks of error, and expediting the drug development process. Other advancements, in remote data collection—including wearable devices and mobile apps—are making it more convenient for people to participate in clinical trials. For example, Pfizer is using wearables for digital mobility assessment that can allow for at-home data collection during clinical trials. Pfizer also utilises devices in our supply chain. For example, with our COVID-19 vaccine Comirnaty™ we have a real-time temperature tracker and geo-fencing device providing us critical insight and ability to proactively act on temperature excursions and delays. This technology is underpinned by mobile technology security and investments. Pfizer is committed to using devices, artificial intelligence, and machine learning to create an autonomous supply chain in the future.

It is hoped the use of this technology will improve speed, reduce errors, and make precision medicine more widely available to patients around the world. However, these incredible technological capabilities can only be leveraged by organisations that have access to the tools, expertise, and expansive healthcare data sets to design and build effective algorithms and accurately interpret the results.

Appropriate governance and regulation for devices, artificial intelligence and big data will be important considerations for the development of medicines in the future, especially as we will begin to see convergence across the healthcare sector with companies with access to big data expanding their offerings. Beyond medicines development and supply, artificial intelligence and data can help to identify more efficient ways to deliver care to patients which could reduce the budget impact of healthcare.

Recommendation: A revised NMP needs to consider incorporating Artificial Intelligence, connected devices and big data in the medicines value chain.

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The importance of diagnostics and genomics for future treatment decisions

An important consideration for the future of precision medicines is genomic profiling and advanced detection. Pfizer supports the view of Omico – a non-profit, incorporated national cancer network providing precision oncology based on genomic medicine – that is proposing to establish a national ecosystem to provide broad-based access to comprehensive genomic profiling (CGP) for relevant cancer patient populations, with its key focus for the first five years in the clinical trials setting.

According to Omico, cancer remains one of the leading causes of death in Australia, yet current treatments are limited in efficacy. Personalised therapies are expected to comprise approximately 80% of the global oncology treatment market within two years. A growing proportion of oncology therapies in clinical trials require biomarker tests for patients enrolling in those clinical trials. CGP is a key enabling technology that identifies these biomarkers and allows physicians to select the most relevant therapies for each patient. To ensure a world-class standard of care is maintained for Australian cancer patients, Australia needs to invest in developing a national ecosystem for CGP and increase the volume of patients participating in biomarker-based clinical trials.^{xiv}

Pfizer remains committed to improving outcomes for cancer patients and has invested in research and understanding of genetic pathways involved in cancer pathogenesis, identification of biomarkers and then developing drugs to effectively target these biomarkers. Using non-small cell lung cancer as an example of precision medicine, we have already seen a complete transformation from a non-targeted chemotherapy approach to a biomarker driven, genetically defined approach, where appropriate patients are directed to targeted therapies. Genomic testing and availability of these tests, therefore, remain pivotal to direct eligible patients to specific targeted therapies.

Wider availability of genomic testing will enable more patients to access appropriate targeted therapies but also drive research and development of newer therapeutics. This will enhance the speed of patient recruitment and increase overall cancer patient participation, both for studies designed by academia and industry. Capturing the importance of biomarkers and genomic testing as part of an improved regime for cancer screening and prevention should be considered as part of the diagnostic and automatic biochemical analysis technologies.

Recommendation: Quality use of medicines needs to recognise the importance of genomic profiling and precision medicine for the advanced detection and diagnosis of certain conditions.

Supporting the global supply chain of medicines

As the largest hospital supplier of sterile injectable products in the country, and a major supplier of Pharmaceutical Benefits Scheme, National Immunisation Program and National Blood Authority listed products, the importance of Pfizer's portfolio in the hospital setting cannot be underestimated. Early in the pandemic response, the TGA developed a list of medicines used for Intensive Care patients during COVID-19 which contained 78 medicines. Pfizer supplies 53 of these medicines, and, for many, we are the sole supplier.

In addition to this Pfizer maintains a sophisticated and complex global manufacturing network of more than 40 sites and over 200 suppliers round the world. In Australia we have two manufacturing locations, Perth and Melbourne which manufacture medicines for use domestically and export to more than 60 countries worldwide.

What COVID-19 has laid bare is that Australia's island geography can serve as an advantage by using our borders to quarantine arrivals and protect the local population, but it also presents a significant challenge with intense pressure on supply chains into and out of the country in times of crisis. If we are to take steps to make Australia more resilient in a global supply chain environment, there must be a recognition that ingredients and components of the end-product come from many sources and have multiple conversion points from raw material to finished product. Pfizer's COVID-19 vaccine for example consists of 280 components from 19 countries around the world.

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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.

Recommendation: The NMP needs to recognise the global context of medicines research, development manufacture and supply and the importance of strong and open global supply chains.

Terms of reference 4: Consider the centrality of the consumer within the NMP and whether it captures the diversity of consumers' needs and expectations.

Recommendation: Consumers should play a pivotal role in the oversight and implementation of the NMP.

Patients are the consumers of health care and are coming to expect the same level of service, convenience and technology enabled solutions in health care as in other parts of their lives.^{xv} Consumers are more active and engaged in access issues than ever before. They are more informed and empowered to take control of their own health. The sheer volume of submissions and engagement in the recent House of Representatives inquiry into novel medicines and medical technologies is a clear indication that patients want more involvement in decision making and policy that impacts them.

To become more patient centric, the revised NMP must engage patients and let them be a driving force behind the development and application of the policy. Patients should have a role in the oversight and review process to ensure it is continuing to meet their needs and expectations.

It will also need to recognise that the digital health revolution is leading to the fragmentation of health information. Increasingly consumers are seeking out their own information before consulting health professionals and making decisions on their treatment pathways based on this initial advice. Our health literacy is more important now than ever. Understanding how the internet has changed our engagement with health information, and whether individuals can successfully evaluate veracity, is an important task.^{xvi} This is because misinformation concerning health has particularly severe consequences regarding people's quality of life and even their risk of mortality.

Recommendation: The NMP needs to reinforce that all partners play a critical role in disseminating trusted, reliable sources of medical information to address fragmentation and misinformation.

Expanding the principle of equity to address health inequity in Australia

Globally, the pandemic has exposed the longstanding structural drivers of health inequities, such as precarious and adverse working conditions, growing economic disparities, and anti-democratic political processes and institutions. These important determinants of health have interlinked with class, ethnicity, gender, education, and other factors to exacerbate existing social vulnerabilities in society. The lasting impact of COVID-19 on the world will be to broaden the economic divide, creating even greater inequities in relation to opportunity, healthcare access and availability.

The Australian Institute of Health and Welfare report into *Australia's health in 2018* found 'all is not equal'. Where you live, how much you earn, whether you have a disability, your access to services and many other factors can affect your health. Overall, Aboriginal and Torres Strait Islander people, people from areas of socioeconomic disadvantage, people in rural and remote locations, and people with disability experience more health disadvantages than other Australians. These disadvantages can include higher rates of illness and shorter life expectancy.^{xvii}

In considering the role of the consumer in a revised NMP the policy needs to address the diverse needs of communities and patients within the Australian healthcare system, paying particular attention to underprivilege and marginalised communities. Pfizer acknowledges that equity is listed as an underlying principle of the revised NMP. This definition should be expanded to include more direct reference to addressing health inequities. Currently, it presumes that we are commencing the new NMP from a level playing field, which we are not.

Recommendation: The NMP needs to expand the principle of equity to actively address existing health inequity.

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Terms of Reference 5: Identify options to improve the NMP's governance; communications, implementation (including enablers) and evaluation.

To ensure the revised NMP remains relevant and fit for purpose there needs to be measurable standards that all partners to the policy can work towards. Currently, the NMP refers to achieving 'optimal health outcomes' and 'economic objectives', however, there are no clear methods or metrics for this to be assessed.

There is no greater incentive to develop novel medicines and medical technologies than predictability and certainty in terms of how studies will be established, how products will be assessed for their safety and efficacy and how their value to the community will be determined.

The benefit of this certainty is that innovative medicines and vaccines made available in Australia, have the potential to generate a significant return on investment in the overall health system and economy as they allow Australians to live longer, healthier, more productive lives. Clear, transparent, agreed goals can provide the same level of certainty for the NMP which will increase its relevance and applicability for all partners going forward. Measures of success of the NMP need to be established and agreed to by all partners taking into consideration the global context of the medicines value chain and comparisons to other countries and their performance.

If all NMP partners are to become 'partners to innovation' it is also important for the NMP to outline how the system assesses, adapts to and values innovation. Part of this will be embracing a broader innovative mindset that reflects the interconnected nature of the medicines value chain, its contribution to the economy and the level of cohesion that exists between partners to bring innovation forward.

Pfizer notes that Medicines Australia has recommended that the review of the NMP must include a thorough review of the governance framework. An NMP governance committee should be formed, consisting of representatives of all NMP partners. The committee should develop a set of metrics to measure progress towards achieving the vision. Pfizer is supportive of this endeavour and remains optimistic that this review will embed the collaboration, horizon scanning, knowledge sharing and benchmarking with international partners that has been evident in our approach to the pandemic and see this applied to broader access challenges.

Finally, there is a clear opportunity for a revised NMP governance framework to stipulate how the NMP will be referenced in closely related health policy activity such as the upcoming reviews of consumer engagement within the PBAC process, the HTA Methods Review and, also, how the final policy will be applied next to Australia's Long Term National Health Plan and other ambitious strategies such as the National Preventive Health Plan.

Recommendation: A revised NMP should communicate to all partners how the principles and pillars will be applied and reviewed over time.

Terms of reference 6: Review the NMP partners and provide options for building greater accountability including addressing conflicts of interest.

As has already been stated by Medicines Australia, *'partnership is key to the delivery of the NMP's ambitions'*^{xviii}. The lasting impact of the pandemic is that it ushered in a new era of partnership in healthcare. The pragmatic and collaborative approach to the pandemic saw common sense decisions to expedite processes, to remove red-tape and to work with health care systems and regulators around the world to deliver medicines to Australian patients.

This review presents an opportunity to apply this collaborative approach to reform and to work towards a simplified, streamlined process that incorporates the views of all stakeholders to improve patient access to medicines in Australia.

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To this extent Pfizer wholly supports Medicines Australia's recommendation to include a forum for discussion between NMP partners, focused on collaboration and resolution of differences, in alignment with the vision for the NMP.

Recommendation: A forum for discussion between NMP partners, focused on collaboration and resolution of differences, in alignment with the vision for the NMP should be established.

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xviii Medicines Australia submission to the NMP review