Department of Industry, Science and Resources
Industry House, 10 Binara Street
Canberra ACT

Dear Committee

Re: Understanding our RNA potential consultation paper

Thank you for providing Pfizer Australia with the opportunity to comment on the RNA consultation.

Pfizer Australia is one of the nation's leading providers of prescription medicines and vaccines. We manufacture and supply 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 and vaccines that are being used to treat and prevent some of the most challenging 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 1,000 colleagues working at two commercial sites, and a manufacturing facility in Victoria, that exports to more than 60 countries.

Pfizer is the global leader in mRNA, with a track record of developing breakthrough vaccines and providing unmatched manufacturing and supply chain solutions. We have been working to protect populations from infectious diseases for more than 100 years and have a rich history in vaccine research and development. Pfizer is committed to working with governments and global health stakeholders by providing solutions to potentially reduce both the human and economic impact of future disease threats.

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

Sincerely,

Anne Harris

Managing Director, Pfizer Australia & New Zealand

Pfizer Australia
L15-18, 151 Clarence Street, Sydney NSW 2000

2. **What characteristics should Australia's RNA sector focus on building over the next 10 years?**

Certain prerequisites underpin the establishment of a well-functioning environment that allows for robust private investment in health. Pfizer believes that a set of core policies make for a healthy market conducive to sustained health investment.

We welcome the opportunity to work with governments to help create the policy framework to attract, investment and create resilient supply chains. Together, these policies create the predictability, efficiency, stability, and sustainability necessary to attract private investment.

These core policies include:

- Predictable and efficient regulatory and reimbursement pathways harmonized with international standards and best practice
- In line with the Strategic Agreement between Medicines Australia and Government, commit to a policy change to:
    - reduce time to access to new health technologies for Australian patients so that they can access new health technologies as early as possible including an agreed, transparent measure of time to access
    - maintain the attractiveness of Australia as a 'first wave' launch country
- Commitment to free trade and open markets
- Strong health infrastructure and secure supply chains
- Whole-of-government commitment to stable, long-term healthcare financing
- Predictable legal and governance environment with IP protections and enforcement
- Support for R&D

The global pandemic showed how RNA technology can transform medicine and vaccines. The success of mRNA vaccines has opened the floodgates for scientific innovation across a vast range of diseases and offers new hope for patients with limited treatment options. The same technology that has helped protect people around the globe from COVID-19 may lead to potential treatments for rare diseases and help prevent other infectious diseases.

Collaboration and Partnerships Drive Innovation

While Pfizer is currently focused on developing mRNA and saRNA vaccines to help prevent the flu, COVID, shingles and to treat rare diseases, we continue to explore other opportunities where the technology could make a transformational impact on patients, and where our expertise has the potential to accelerate the pace of innovation. We are also exploring combination vaccines for a range of respiratory diseases, utilising RNA and non-RNA technology.

To further build our internal capabilities, collaboration and partnership are key elements of Pfizer's mRNA strategy. A variety of licensing and research collaborations have been initiated to further the development of RNA-based vaccines and treatment options.

Global Centres for Therapeutic Innovation

Many advances in medicine are achieved through global collaboration. At Pfizer, Centres for Therapeutic Innovation (CTI) facilitate authentic collaboration between scientists and select academic medical centres across the world and disease foundations. The aim is to translate promising science into clinical candidates,

wherever across the globe it occurs. Our dedicated "RNA Accelerator" enterprise establishes academic collaborations and initiates exploratory projects through Pfizer's Center for Therapeutic Innovation.

Pfizer's CTI partners are given unprecedented access to our antibody/small molecule library and technologies and can draw upon Pfizer's expertise.
Authentic collaboration includes:

- shared decision making
- shared accountability
- each project is overseen by a joint steering committee to evaluate the success of the program and monitor progress toward milestones
- alignment on incentives
- joint IP and ownership, broad rights to publication, milestone payments and royalties for successful programs

4. Which elements of the RNA technology development and supply chain should Australia focus on developing sovereign capability in?

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 patient access. With years of manufacturing experience on our side, we've arguably developed the most efficient vaccine manufacturing capability that the pharmaceutical industry has seen.

Supply of mRNA vaccines for the COVID pandemic
Over the years, Pfizer has built a flexible and diverse supply chain that can handle sudden shortfalls and produce new products. At Pfizer, we have long known that mRNA could be the key to a different future where medicines and vaccines harness the body's own cellular power to prevent or treat disease. In 2018, Pfizer started exploring mRNA platforms for flu vaccines with BioNTech, so when the pandemic hit, Pfizer was poised to develop the manufacturing of a mRNA COVID-19 vaccine. The flexibility of mRNA would also allow us to alter the vaccine to address new strains quickly.

We have been innovative and broken new ground as we work to ensure our mRNA vaccines reach the people who need them. The temperature logistics team developed a shipper not only to transport temperature-sensitive vaccines around the world but that could also serve as a temporary freezer for sites that do not have ultra-cold infrastructure. We plan to use this innovation to transport other temperature-sensitive medicines in the future, allowing us to reach underserved patients in rural areas. We teamed up with leaders in remote drone delivery to get shipments of some of our most critical vaccines to rural communities in Ghana – where poor road accessibility, changing weather conditions, or geographic features can impede traditional distribution methods – and set a new industry standard in critical medicine delivery.

We continue to work with diverse suppliers across our supply chains to spread risk and maintain the resilience of our supply chains. We also partnered with more than 300 diverse suppliers and contract manufacturers and added dozens of qualified and capable small businesses to our network, which helped us boost diversity and reliability within our supply chain. To manufacture our most critical vaccines, we put in place two parallel supply chains – one in the U.S. and one in Europe – to ensure that we could provide our vaccine to patients all over the world as quickly as possible. Appropriate redundancies and flexibility

within our supply chain, including extra inventory, increasing workers, and using multiple suppliers, help us remain resilient.

Best practice for resilient supply chains

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

No single country can produce every health product it needs. Onshoring manufacturing is a solution for products with less complexity. No country globally has a sovereign end to end manufacturing and supply chain. Even in a scenario where much of the production of a complex vaccine is completed in a single country, such as Australia, the registered starting materials and critical reagents still need to be brought in from overseas because no single country has the capacity to resource the end-to-end supply chain for therapies as complex as mRNA vaccines.

If we are to take steps to make Australia more resilient in a global supply chain environment, we must recognise that ingredients and components of the end product come from many sources and have multiple conversion points from raw material to finished product. Maintaining uninterrupted supply chains across borders and globally integrated value chains make this possible and are critical to our health security.

Global supply chains for vaccines 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. There are inherent risks to centralising vaccine production in a single country. When production is centralised in a single country, in the event of a supply chain interruption, a facility that relied on imports of key ingredients for domestic production could no longer operate. This situation is unlike global supply chains where ingredients are sourced from multiple locations and there are multiple translation points in multiple locations that occur in the production of the vaccine.

One way to manage the inherent risk of centralising production in a single country is to ensure procurement is adequately diversified. In order to be aligned with the recommendations of the Halton review, a portfolio approach will continue to be needed to mitigate the risk of supply shortage, delays, lack of success in clinical trials, manufacturing or regulatory failure. The Review strongly reinforced 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."[i]

5. What are the barriers to uptake?

A challenging health technology assessment (HTA) environment

Vaccines are uniquely valuable as they provide protection against infectious diseases which often have limited treatment options and cause significant morbidity in otherwise healthy populations, and can also provide benefits to unvaccinated individuals through reduced infection risk (i.e. herd immunity).

The Australian access environment for innovative vaccines is increasingly challenging and threatens the shared goal of the HTA review to maintain Australia's attractiveness as a first launch country. Australia must revisit the criteria for attribution of value to vaccines to ensure that the vaccines of the future can be made available to Australians in an equitable, timely manner.

The PBAC utilises well-established HTA principles, among other factors, in determining the value of vaccines to the community, however these are not always fit for purpose. These principles can disadvantage vaccines compared to medicines, in some of the following ways:

- the high discount rate of 5% applied to future costs and benefits for all interventions means vaccines appear less cost-effective given it often takes time for the benefits of vaccines to accumulate i.e. in contrast to medicines, all costs are paid at the time of vaccination, but the health benefits accrue over decades;
- the narrow assessment scope which usually looks at the benefits/costs relevant to the individual and the healthcare system rather than the broader benefits to the community (for example, vaccination that prevents illness that causes long term disability not only impacts the individual but also their family and community who become carers); and
- the low cost-effectiveness threshold applied to preventive interventions like vaccines (compared to therapeutic medicines) means lesser value is being placed on the population health benefits which can be achieved through vaccination.

Australia's constrained approach to vaccines leads to public underinvestment in prevention. The short budget cycle creates a perverse incentive to favour treatment over prevention. With a change in approach, a virtuous cycle could be created in which Government invests in health promotion through vaccines which incentivises vaccine research and development which in turn will mean more innovative vaccines will become available. Vaccines are one of the most effective ways to reduce the global infectious disease burden and support the control and prevention efforts against antibiotic resistance. Their health, economic, and societal value should be considered appropriately.

An inadequate regulatory data protection period to drive local investment, innovation and affordable patient access to breakthrough medicines and vaccines

An intellectual property (IP) policy environment that includes, for example, a strong patent system and regulatory data protection, is critical to incentivise and drive the extensive investments and risks involved in the development of innovative medicines. 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 medicines.

A strong and effective IP system is of significant importance to the biopharmaceutical industry, where on average it takes at least 10-15 years to bring a medicine from drug discovery through approval to market. The term of patent protection is 20 years from the filing date, subject to extension in limited circumstances, leaving approximately 5-10 years for innovative companies to recover the extensive research and development investments and fuel the next generation of breakthrough therapies.

Added to that, the costs of R&D of new medicines have increased substantially in recent decades, with

the average cost of bringing a breakthrough medicine to market now at US$2.6bn.[ii] Once market exclusivity expires, generic competitors can enter the market, and at that point the price paid to the innovator by the Commonwealth automatically reduces by 25% for PBS listed medicines, with further reductions driven through the PBS' ongoing simplified pricing disclosure process.

As part of the development of new medicines, companies conduct clinical trials to test the benefits and risks of a potential medicine and determine the impact of such treatment. Pfizer, for example, is currently investing in ~65 global clinical trials in Australia. However, compounding the cost of development is the significant risk of the innovative process, with the overall probability of clinical success dropping from 21.5% to 11.8% since the 1990's.[iii]

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.

During previous trade negotiations, such as the Trans-Pacific Partnership in 2015, Commonwealth representatives opposed extending Australia's RDP term due to concerns it could delay savings measures on reimbursed medicines. At this time the first statutory price reduction on a PBS-listed medicine was triggered by the entry of a competitor product. In recent years the innovative medicines industry has supported the implementation of significant reforms which incorporate statutory price reductions to medicines at five, 10 and 15 years after listing on the PBS.vi These price reductions are applied regardless of patent validity, RDP term or entry of a competitor product, thereby countering the previous concerns.

These recent changes have placed Australia in a position to benefit from an extended RDP term, thereby creating a level playing field for Australian companies compared to the EU and the US and delivering a significant boost to the Australian economy and earlier access to innovative medicines for patients, whilst retaining the integrity of the PBS and strong savings measures on listed medicines. Pfizer Australia is committed to working in partnership with the Australian Government to drive our shared goal of affordability and access to medicines for those most in need. The Commonwealth's ongoing commitment to patent protection and a stronger position on regulatory data protection will position us well to attract foreign investment and drive medicines access throughout this pandemic period and beyond.

---

[i] Halton (2022) Review of COVID-19 Vaccine and Treatment Purchasing and Procurement - https://www.health.gov.au/resources/foi-disclosure-log/foi-4062-release-document-halton-review

[ii] Pham D.N. & M. Donovan (2019), "The Declining Trend of Pharmaceutical Expenditures in U.S. FTA Partner Countries", NDP Analytics.

[iii] DiMasi J.A., H.G. Grabowski, & R.W. Hansen (2016), "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs." Journal of Health Economics.