Responses from Pfizer Australia to Questions on Notice from Senate Standing Committee on Education and Employment re Inquiry into COVID-19 Vaccination Status (Prevention of Discrimination) Bill 2022 and the Fair Work Amendment (Prohibiting COVID-19 Vaccine Discrimination) Bill 2023

Vaccines are one of the greatest public health advancements of all time, resulting in the control, eradication, or near-elimination of numerous infectious diseases that were once pervasive and often fatal. On par with access to clean water and good sanitation, vaccines safeguard our communities and help ensure that healthy people stay well, productive, and active.

At Pfizer, we believe vaccination is one of the best ways possible to help protect infants, children, and adults against infectious diseases. Our aspiration is to fundamentally transform infectious disease prevention so that people of all ages can live longer and healthier lives.

Our rich history in vaccine research, development, and delivery dates back more than a century. Over the years, Pfizer – including its predecessor companies – has played a pivotal role in eliminating or nearly eliminating deadly infectious diseases like smallpox and polio globally. We have designed and developed breakthrough protein-based and mRNA-based vaccines designed to prevent certain viral and bacterial diseases like those caused by *S. pneumoniae, N. meningitidis*, and, in collaboration with BioNTech, SARS-CoV-2.

Today, more people benefit from vaccines to help prevent infectious diseases than ever before at all stages of life, from infants to seniors. We are proud of our contributions to this profound public health impact, including delivering the first authorized COVID-19 vaccine with our collaborator BioNTech in 2020, and in 2022 we produced more vaccine doses than any other vaccine manufacturer in the world.

Still, we know our work is not done. From changing climates that now allow certain pathogens to thrive and increased movement to urban areas, to people traveling within and across borders, the world faces a number of realities that all facilitate the transmission of infectious diseases – including global pandemics such as COVID-19. Working to ensure equitable access and accelerate the availability of potentially life-saving vaccines around the world is a key component of our commitment to improving global health.

Our industry-leading pipeline, scientific expertise and end-to-end global capabilities put Pfizer at the forefront of a new era of vaccine innovation to help address these realities. We continue to advance our leadership in vaccines against pneumococcal and meningococcal disease, deliver breakthroughs to help prevent respiratory syncytial virus (RSV) in older adults and infants from birth through age 6 months via maternal immunisation, and explore the potential of vaccines to help protect against other diseases like maternal Group B streptococcus bacteria (GBS) and an mRNA-based flu vaccine. Driving our efforts are the many millions of lives around the world that are depending on us.

Vaccines are one of the greatest advancements for improving public health, allowing people to grow, thrive, and contribute to their communities. They have freed generations of children and adults from serious, often life-threatening diseases that were once widespread and oftentimes fatal. Vaccines are estimated to prevent millions of deaths annually across the globe, which can translate to reduced healthcare costs and improved economic stability.

The COVID-19 pandemic underscores the impact of vaccines and the importance of protecting against vaccine-preventable diseases. That is why Pfizer invests resources and expertise in uncovering the next vaccine innovations to potentially help ensure that people of all ages are able to benefit from immunisation programs that can address vaccine-preventable diseases.

Pfizer is changing the outcome of devastating diseases through science. We have a 175-year track record of researching, developing, manufacturing, and delivering innovative medicines and vaccines, some of which have eliminated or nearly eliminated deadly infectious diseases.

Over the past decade, Pfizer has worked with focus and rigour to build the capabilities that have allowed us to substantially grow the number of vaccine programs in the clinic – and most recently, to move quickly and effectively to take on COVID-19, the disease caused by SARS-CoV-2 infection. Our efforts over the past 10 years have bolstered Pfizer's leadership in the vaccine space anchored in three key strengths: innovation, portfolio breadth and depth, and scale. We have invested significantly in our vaccine infrastructure and operate one of the most sophisticated and reliable supply chains in the industry, as evidenced by our COVID-19 vaccine distribution.

From the outset of the COVID-19 pandemic, we committed to using our capabilities and resources to help address the crisis as quickly as possible while maintaining the trust of regulatory authorities, healthcare providers, and – most importantly – the public. We are applying learnings from our groundbreaking COVID-19 vaccine efforts, and the same entrepreneurial and collaborative spirit, to our promising vaccine pipeline – with the goal of delivering more vaccine breakthroughs to the world.

In confronting the COVID-19 pandemic, the defining global health crisis of our time, Pfizer quickly pivoted resources to develop a breakthrough COVID-19 vaccine in collaboration with BioNTech. Our long-standing experience in vaccine development and distribution laid the foundation to quickly scale, manufacture, and distribute large quantities of a COVID-19 vaccine globally.

While the World Health Organization declared the end of the COVID-19 global public health emergency in May 2023, it remains important to take a proactive approach to protecting against, testing for, and treating COVID-19, especially due to the highly mutative nature of the disease. Staying up to date with vaccinations is the first line of defense to prevent hospitalisation and death.

Pfizer remains committed to following the science to stay vigilant against the virus and emerging variants. We continue to evaluate vaccine candidates as part of a long-term scientific COVID-19 vaccine strategy to potentially generate more robust, longer-lasting, and broader immune responses to help protect against COVID-19 disease. With BioNTech, we are also exploring multiple vaccine combinations, including flu/COVID and a flu/COVID/RSV triplet, as part of our longer-term strategy.

Please find below answers to questions on notice received shortly before the tabling of the final report and completion of this inquiry. Whilst many of the questions were not relevant to the terms of reference of the inquiry, Pfizer provides the below responses in good faith which have been grouped together by subject matter to reduce repetition.

Thank you again for the opportunity to assist the Senate with its work and to participate in this inquiry.

Response in relation to questions received on adverse events:

Vaccine safety remains of utmost priority for Pfizer. We take adverse events that are potentially associated with our COVID-19 vaccines very seriously. We closely monitor all such events and collect relevant information to share with global regulatory authorities.

We have extensive clinical experience with several COVID-19 vaccines. With hundreds of millions of doses administered globally, the benefit-risk profile of our vaccines remains positive for all authorised indications and age groups.

It is important to note that serious adverse events that are unrelated to the vaccine are unfortunately likely to occur at a similar rate as they would in the general population.

In relation to questions on carcinogenicity and genotoxicity studies:

No signs of DNA mutation or COVID-19 vaccine-induced cancer have been reported to date for the Pfizer-BioNTech COVID-19 vaccine. This refutes claims made on September 12, 2023 during a Pandemic Preparedness Listening Session hosted by the US Senate Medical Affairs. During the session, the Committee heard remarks pertaining to the Pfizer-BioNTech messenger RNA (mRNA) COVID-19 vaccine, incorrectly stating that the vaccine could potentially impact a person's DNA and be a theoretical cancer risk. There is no evidence to support these claims.

Specifically, these claims allude to SV40, which stands for Simian Virus 40, a naturally occurring DNA virus originating with monkeys. In the 1960s, some polio vaccines were found to be contaminated with infectious SV40 virus, exposing those receiving the contaminated vaccines to infectious virus. Infectious SV40 virus is not in the Pfizer-BioNTech COVID-19 vaccine.

In relation to questions on clinical trial study methodology and on vaccine effectiveness:

The original Pfizer-BioNTech COVID-19 vaccine (introduced in 2020) underwent extensive human clinical trials prior to authorisation by regulatory bodies around the world including FDA, EMA and ATAGI.

In our initial vaccine clinical trials, we ensured that trials were inclusive of populations that are more vulnerable or where burden of disease has been higher. Our stage 3 clinical trial enrolled 46,331 participants at 153 sites in Brazil, Argentina, Germany, Turkey, South Africa and the United States. Approximately 42% of global participants and 30% of U.S. participants in the Phase 3 study had racially and ethnically diverse backgrounds. And, we are continuously investing in research and trials for different formulations of our vaccine that will improve stability, enabling greater access in communities where infrastructure may not support the cold chain requirements of our vaccine.

To date, pre-clinical data have reliably predicted the clinical response across several variants, including the wild-type virus, Omicron BA.1, Omicron BA.4/BA.5, and Omicron XBB.1.5. The updated COVID-19 vaccine will differ from our current COVID-19 vaccine only in that they contain mRNA coding for the spike proteins of a different SARS-CoV-2 sublineage.

Given the strong safety and efficacy track record of mRNA COVID-19 vaccines among hundreds of millions of adults and children around the world, the International Coalition of Medicines Regulatory Authorities has reached consensus that strain changes should require only pre-clinical and manufacturing data at the time of authorisation, in order to more closely match circulating strains.

This is the same process by which the 2023-2024 Omicron XBB-adapted monovalent vaccine was authorised for both adults and children.

Pfizer's updated COVID-19 vaccine, designed for the Omicron XBB.1.5 subvariant (Kraken) only differs from earlier COVID-19 vaccines in that it contains mRNA coding for the spike protein of a different SARS-CoV-2 sublineage.

In relation to questions on confidentiality:

The advance purchase agreement between Pfizer and the Commonwealth of Australia is a commercial-in-confidence document, and we are unable to comment further.

In relation to questions on contaminants:

Vaccine safety remains of utmost priority for Pfizer. We have extensive clinical experience with several COVID-19 vaccines. With hundreds of millions of doses of the original and Omicron BA.4/BA.5-adapted bivalent Pfizer-BioNTech COVID-19 vaccine administered globally, the benefit-risk profile of our vaccines remains positive for all authorised indications and age groups.

In relation to questions on employee batches of vaccines:

The Pfizer employee batches sent to Australia were exactly the same vaccine as those provided to the broader community. Pfizer chose to provide extra doses to the amount secured by the Commonwealth in the advance purchase agreement so that Pfizer employees would not draw down on Australian stocks.

This also enabled Pfizer Australia to be able to conduct an in-house vaccination program, however many Pfizer employees received their vaccine through the public program as they were eligible to receive it prior to the in-house vaccination date. Any booster doses received by employees have been through the public program.

In relation to questions on gene therapy:

MRNA vaccines do not alter your DNA, or interact directly with your DNA at all.

In relation to questions on immune responses:

Many individuals have questions about the benefits of vaccine-induced immunity over natural immunity received from contracting COVID-19. Natural immunity comes from exposure to a bacteria or virus through infection, while vaccine-induced immunity teaches our bodies how to fight bacteria or virus without meeting the live version of it. An mRNA vaccine builds immunity by delivering sets of instructions to the body's immune system to help fight disease from bacteria or viruses.

COVID-19 vaccination provides a predictable immune response, and real-world evidence indicates that people can build added protection by getting vaccinated after contracting COVID-19, making them less likely to contract COVID-19 again. So, even if a person has had COVID-19, they should still get vaccinated, particularly because we do not know the long-term effects of COVID-19 and having a mild case does not guarantee that subsequent infections will also be mild.

In relation to questions on influencing the government narrative:

Pfizer fully respects the independence of government regulatory bodies. Information released by the Therapeutic Goods Administration is the responsibility of that body.

In relation to questions on lipids:

We have an established, well-proven research and development organisation. The end-to-end process, with established leaders in their field, ensures that we link the biology of the disease with the vaccine that we are making. Vaccines are biologics and this is an important factor to consider. One of the key advantages is our global manufacturing footprint. This is something few companies in the industry have and we believe will be a differentiator for us in the future.

We're focused on developing formulations for future mRNA vaccines and therapeutic candidates with lipid nanoparticle compositions that help to increase stability, enhance efficacy, and improve tolerability. We have made important investments in LNP formulation technology and mRNA manufacturing technology with the goal to accelerate our efforts.

In relation to questions on lobbyists:

Pfizer Australia has not contracted external professional lobbyists to perform lobbying activities on its behalf related to the approval of the COVID-19 vaccine.

In relation to questions on Long COVID:

This matter was explored in detail by the House of Representatives Committee on Health, Aged Care and Sport's Inquiry into Long COVID and Repeated Infection and its report: *"Sick and tired: casting a long shadow".* Pfizer provided evidence at a public hearing of that inquiry.

In relation to questions on long term immunity:

Vaccine-Acquired Immune Deficiency Syndrome (VAIDS) is not a condition that is recognised by expert medical communities. COVID-19 vaccines work by triggering the body's natural immune response and there is no biologically plausible mechanism by which immunity would be reduced to either COVID-19 or other infections. There is no evidence that receiving COVID-19 vaccines can result in immunodeficiency.

In relation to questions on vaccine mandates:

Mandates or vaccine requirements are determined by local governments and health authorities.

In relation to questions on mRNA safety:

Vaccine safety remains of utmost priority for Pfizer. We take adverse events that are potentially associated with our COVID-19 vaccines very seriously. We closely monitor all such events and collect relevant information to share with global regulatory authorities.

We have extensive clinical experience with several COVID-19 vaccines. With hundreds of millions of doses administered globally, the benefit-risk profile of our vaccines remains positive for all authorised indications and age groups.

It is important to note that serious adverse events that are unrelated to the vaccine are unfortunately likely to occur at a similar rate as they would in the general population.

In relation to questions on mRNA sequence:

With COVID-19, we are facing a virus with an exceptionally high mutation rate, which the nimble mRNA platform is well situated to address because only the mRNA sequence requires updating to match emerging strains. Having established safety and efficacy of our mRNA COVID-19 vaccines among hundreds of millions of adults and children around the world over the past three years, we are poised to rapidly produce updated vaccines that match circulating strains, similar to the way influenza vaccines are updated each year.

Pending regulatory acceptance of each new variant vaccine, this approach would help address the pressing need for vaccines that provide a high level of protection against current and emerging variants of concern, so that we can remain vigilant against this evolving virus.

We are also working to develop COVID-19 vaccines designed to potentially provide broader and longer-lasting protection against severe disease and hospitalisation.

In relation to questions on mRNA stability:

We have an established, well-proven research and development organisation. The end-to-end process, with established leaders in their field, ensures that we link the biology of the disease with the vaccine that we are making. Vaccines are biologics and this is an important factor to consider.

One of the key advantages is our home-grown, global manufacturing footprint. This is something few companies in the industry have and we believe will be a differentiator for us in the future.

We're focused on developing formulations for future mRNA vaccines and therapeutic candidates with lipid nanoparticle compositions that help to increase stability, enhance efficacy, and improve tolerability.

In relation to questions on reported cases of myocarditis and pericarditis:

Vaccine safety remains of utmost priority for Pfizer. We take adverse events that are potentially associated with our COVID-19 vaccines very seriously. We closely monitor all such events and collect relevant information to share with global regulatory authorities.

With hundreds of millions of doses of the original and Omicron BA.4/BA.5-adapted bivalent Pfizer-BioNTech COVID-19 vaccine administered globally, and more than 4.6 billion vaccines delivered overall, the benefit-risk profile of our vaccines is well established and remains positive for all authorised indications and age groups.

To date, hundreds of millions of people around the world have received our vaccines, and serious adverse events that are unrelated to the vaccine are likely to occur at a similar rate as they would in the general population.

It is important to note that every medicine – and vaccine – has side effects. But all approved medicines and vaccines are rigorously tested in clinical trials to ensure the side effects are manageable and the benefits outweigh the risks.

Pfizer is aware of rare reports of myocarditis and pericarditis, predominantly in male adolescents and young adults, after mRNA COVID-19 vaccination. According to public health and regulatory authorities around the globe, the number of reports is small given the number of doses administered and patients have typically rapidly improved with conservative treatment. It is important to note that global regulatory authorities and medical societies continue to recommend COVID-19 vaccinations.

In relation to questions on Norway nursing home deaths:

Pfizer and BioNTech are aware of reported deaths in some Norway nursing homes following administration of BNT162b2.

Norwegian Authorities have prioritised the immunisation of residents in nursing homes, most of whom are very elderly with underlying medical conditions and some of whom are terminally ill. The Norwegian Medicines Agency has reported while a possible connection in the most vulnerable patients cannot be ruled out, they have confirmed there is no evidence of a direct link between the deaths and vaccination.

The Norwegian Institute of Public Health has clarified its vaccination guidance for severely frail patients (for example equivalent to Clinical Frailty Scale 8 or higher) and terminally ill patients including a careful assessment of the benefit versus risk of the vaccination.

In relation to questions on plasmid DNA:

There is no evidence to support claims that the Pfizer-BioNTech COVID-19 vaccine contains plasmid DNA that could potentially impact a person's DNA or be a theoretical cancer risk.

The Pfizer-BioNTech COVID-19 vaccine has been reviewed by multiple regulatory authorities, including the EMA and U.S. Food and Drug Administration (FDA), and advisory bodies globally and has met all safety and quality control guidelines. These agencies approved our COVID-19 vaccine with established specifications for development and manufacturing, including a validated method for assessment of residual DNA outlined by the World Health Organization and FDA for biological products.

It is important to note that similar quality standards regarding residual DNA are applied to other vaccines. Small amounts of residual DNA can be found in several approved vaccines, including influenza and hepatitis vaccines, which have been administered globally for more than 30 years.

Since its initial authorisation for use in December 2020, the Pfizer-BioNTech COVID-19 vaccine has been administered to more than 1.5 billion people, has demonstrated a favourable safety profile in all age groups, and has helped protect against severe COVID-19 outcomes, including hospitalisation and death.

In relation to questions on political donations:

Pfizer discloses all Australian political contributions through the annual public disclosure process administered by the Australian Electoral Commission.

In relation to questions on pregnancy risk:

In the fourth quarter of 2021, enrollment was stopped in C4591015 Study (a Phase 2/3 placebo controlled randomized observer-blind study to evaluate the safety, tolerability, and immunogenicity of BNT162b2 against COVID-19 in healthy pregnant women 18 years of age and older). This study was developed prior to availability or recommendation for COVID-19 vaccination in pregnant women.

The environment changed during 2021 and by September 2021, COVID-19 vaccines were recommended by applicable recommending bodies (e.g., ACIP in the U.S.) for pregnant women in all participating/planned countries, and as a result the enrollment rate declined significantly. With the declining enrollment, the study had insufficient sample size to assess the primary immunogenicity objective and continuation of this placebo-controlled study could no longer be justified due to global recommendations. This proposal was shared with and agreed to by FDA and EMA.

It is important to note that relevant real-world evidence on the use of COVID-19 vaccines in pregnant women has been presented and published numerous times by various parties in multiple journals and forums, including a publication in The BMJ showing studies of people receiving COVID-19 vaccination during pregnancy have not identified pregnancy-related safety signals.

In relation to questions on social media:

Pfizer has LinkedIn, Facebook, Twitter, and Instagram pages.

In relation to questions on the spike protein:

We have extensive clinical experience with several COVID-19 vaccines. This season's COVID-19 vaccine differs from earlier COVID-19 vaccines only in that it contains mRNA coding for the spike protein of a different SARS-CoV-2 sublineage. With hundreds of millions of doses of the original and Omicron BA.4/BA.5-adapted bivalent Pfizer-BioNTech COVID-19 vaccine administered globally, the benefit-risk profile of our vaccines remains positive for all authorised indications and age groups.

We are continuing to pursue COVID-19 vaccines, including vaccine candidates containing mRNA that codes for enhanced prefusion spike proteins or T-cell antigens, with the aim of improving durability of response and breadth of protection. These vaccine candidates are part of Pfizer and BioNTech's multifaceted approach toward remaining vigilant against the evolving SARS-CoV-2 virus.

In relation to questions on the TGA cost recovery process:

The Therapeutic Goods Administration charges all entities submitting documentation for regulatory approval under a cost recovery basis. The amount charged and the activities supported by this funding are a matter for the Therapeutic Goods Administration.

In relation to questions on vaccine injury:

Vaccine safety remains of utmost priority for Pfizer. We take adverse events that are potentially associated with our COVID-19 vaccines very seriously. We closely monitor all such events and collect relevant information to share with global regulatory authorities.

We have extensive clinical experience with several COVID-19 vaccines. This season's COVID-19 vaccine differs from earlier COVID-19 vaccines only in that it contains mRNA coding for the spike

protein of a different SARS-CoV-2 sublineage. With hundreds of millions of doses of the original and Omicron BA.4/BA.5-adapted bivalent Pfizer-BioNTech COVID-19 vaccine administered globally, the benefit-risk profile of our vaccines remains positive for all authorised indications and age groups.

In relation to questions on variants:

Pfizer continues to closely monitor emerging variants. We're working with public health bodies on the composition of the 2024-2025 COVID-19 vaccine formula and are making appropriate preparations in an effort to ensure we are ready to meet the public health need globally.

In relation to questions on the BMJ article re Ventavia:

Pfizer has a robust quality management system in place for all aspects of our clinical trials, as they are the foundation of our commitment to patient safety and the integrity of our trials. We take all concerns raised very seriously and thoroughly investigate them, and when necessary take swift action to address challenges or issues.

We are disappointed by the article published by the British Medical Journal that failed to contact us prior to publication and selectively reported certain claims with the goal of undermining confidence in a vaccine that has been given to hundreds of millions of people worldwide.