Senate Standing Committee on Education & Employment Inquiry
Pfizer statement in response to the additional questions on notice (September 2023)

Pfizer notes that some written questions on notice duplicated questions asked of us during the hearing as well as questions taken on notice to which we have already responded. In order to assist the Committee with its Inquiry, we made our experts available and answered all questions put to us. We note that the Inquiry has now concluded and that the report of the Committee was published on 25 August and recommended the Senate not pass the Bills. Pfizer provides the following statement in acknowledgement of and in response to the additional questions.

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines.

For over a century, Pfizer has been at the forefront of helping to reduce the threat of deadly infectious diseases through the development of novel vaccines and medicines based on new delivery systems and technology.

Pfizer is one of the largest sterile injectables suppliers in the world, producing more than one billion sterile units per year.

Last year more than one out of every six people worldwide are estimated to have used a Pfizer medicine or vaccine. As of June 4, 2023, we have delivered more than 4.6 billion COVID-19 vaccine doses to 181 countries and territories in every region of the world. These numbers represent real people around the world who were helped by what Pfizer scientists developed and brought to patients.

Pfizer has confidence in the safety of our vaccine. Given the urgent public health need to develop a vaccine in a safe and responsible way, we collaborated closely with independent regulatory and health authorities around the world to conduct key activities in parallel, to allow us to significantly accelerate vaccine development without compromising safety.

In the usual drug development journey, the process of preparing regulatory data is iterative. We prepare packages of data to submit to regulators - such as the FDA and the EMA as well as the TGA - and then wait to hear back in a process which often takes months.

With all hands-on-deck in the fight against COVID-19 across the globe, regulators responded to data very quickly, often in real time, to help keep trials running as efficiently as possible.

Pfizer has the utmost respect for all regulatory authorities, and for upholding the integrity of their scientific review process as they evaluate the data for our vaccine candidate. Science has and will always guide our efforts without compromise.

The independent data monitoring committee for our landmark trial did not report any serious safety concerns related to the vaccine prior to licensure. The data demonstrates the vaccine is well tolerated across the authorised indications across all the age groups.

Since its FDA authorisation in 2020, Pfizer's COVID-19 vaccine has been administered to hundreds of millions of people globally and continues to be vigilantly monitored through

clinical trials and post-authorisation surveillance. The vaccine has received full regulatory approval in a variety of countries including the US, EU and Australia following earlier emergency use, conditional and provisional approvals.

These authorisations are based on robust and independent evaluation of the scientific data on quality, safety, and efficacy, including our landmark phase 3 clinical trial. Data from real world studies complement the clinical trial data and provide additional evidence that the vaccine provides effective protection against severe disease.

We note also that global regulators are continually assessing the vaccine safety data in their regions. The International Coalition of Medicines Regulatory Authorities (ICMRA) – a group of 38 medicines regulatory authorities – recently released a statement confirming the safety profile of COVID-19 vaccines. The global regulators stated that evidence from more than 13 billion doses of COVID-19 vaccines administered worldwide show that these vaccines have a very good safety profile in all age groups, including children and people with underlying medical conditions, immunocompromised patients and pregnant women. They stated the vaccines have saved millions of lives worldwide by significantly reducing the risk of severe disease, hospitalisation and death from infection with SARS-CoV-2.

We take adverse events that are reported for our COVID-19 vaccine, BNT162b2, very seriously. We closely monitor reported adverse events and share them and other relevant safety information with regulatory authorities according to country regulations. Based on ongoing safety reviews performed by Pfizer, BioNTech and health authorities, BNT162b2 retains a positive benefit-risk profile for the prevention of COVID-19 infections.

We have engaged in an unprecedented level of transparency in our development and supply of COVID-19 vaccines. It started with our commitment to openly sharing the details of our clinical trial program and publishing data in peer reviewed journals.

Pfizer is proud of the collaboration we have had with the Australian Government to deliver timely and reliable access to our COVID-19 vaccine, and we look forward to continuing that partnership to ensure Australia is even better prepared for future threats to public health.