Questions on notice
Pfizer Australia Pty Ltd ("Pfizer") provides the following responses in relation to the supply of Comirnaty in Australia:

What evidence did Pfizer have for their statement on Twitter on 14 January 2021 that the vaccine would help stop transmission? (Senator Canavan)

- We have been open and transparent about the data we have available from the very initial days of this pandemic, and have shared what we know as we've known it. Initial data from our landmark clinical trial indicated that the vaccine might prevent transmission; however, this was not a primary endpoint of the study. As the vaccine was administered broadly and new variants emerged, we learned more about transmission through real-world studies.
- Regulatory agencies across the world have authorised the use of BNT162b2 (Comirnaty) for the indication of active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus.
- The authorisation of BNT162b2 (Comirnaty) is based on robust and independent evaluation of the scientific data on quality, safety and efficacy, including our landmark phase 3 clinical trial, that was designed in agreement with regulatory authority requirements. The pivotal BNT162b2 clinical trial efficacy end-point was prevention of confirmed symptomatic COVID-19 infection.
- The BNT162b2 (Comirnaty) trials were not designed to evaluate the vaccine's effectiveness against transmission of SARS-CoV-2.
- There are a number of independent real-world data studies which have reported some benefit of COVID-19 vaccination on reduction of disease transmission. This benefit has differed based on the variant that was dominant during the study periods.
- There is extensive data showing that COVID-19 vaccines are effective, have positive benefit/risk profile, and have prevented millions of COVID-19 symptomatic cases and millions of hospitalisations and deaths.
- Transmission of SARS-CoV-2 depends on various factors like circulating dominant variant, host characteristics like - age, mobility, comorbid conditions, pharmaceutical and non-pharmaceutical interventions, overall population vaccination coverage, asymptomatic infections, waning immunity, socio-economic and living conditions, etc.
- As per the World Health Organisation, there could be a modest impact on transmission for the mRNA vaccines.
- Real world data has shown some benefit of vaccination for preventing asymptomatic infections due to SARS-CoV-2.

On 8 June 2021 Albert Bourla Tweeted that the vaccine was a critical tool in stopping transmission. What evidence was there to support that statement? (Senator Canavan)

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How much funding does Pfizer provide to the TGA per annum? (Senator Antic)

- Like any pharmaceutical company seeking to register a therapeutic good (medicines and medical devices) in Australia, Pfizer must seek regulatory approval from the TGA, which acts completely independent of industry in its decision making. The evaluation process occurs on a cost-recovery basis whereby the applicant pays a fee to cover the administrative costs associated with evaluation of the applications to register a therapeutic good, regardless of the outcome.
- Similarly, for the sponsor of the therapeutic goods to maintain supply, they must continue to comply with the conditions of the registration, including relevant legislative requirements and guidelines. Pfizer must provide scientific data updates to the TGA for compliance with the conditions, and pay a fee to the TGA for the assessment of that data.
- A full list of fees and charges imposed by the TGA is available here: https://www.tga.gov.au/how-we-regulate/fees-and-payments/summary-fees-and-charges/summary-fees-and-charges-applications-submitted-tga.
- The total fees paid by Pfizer changes from year to year as it is dependent on the number of new therapies being brought forward for registration and how many therapeutic goods are included in the Australian Register of Therapeutic Goods (ARTG) at any one time. This changes from time to time as therapies are acquired or sold.

Has Pfizer notified its underwriters of the possibility of liability for future claims or will those claims be offset because of the indemnity provided by the Australian government? (Senator Antic)

- Pfizer has complied with all relevant laws in supplying Comirnaty. Pfizer stands behind the safety and efficacy of its vaccine. We cannot comment on any specific legal matters.

Is it true the Pfizer COVID vaccine was developed initially as a counter-measure for the American Department of Defence? (Senator Roberts)

- Pfizer's COVID vaccine was not developed as a counter-measure for the US Department of Defence.

Did Pfizer have any conversations with any Australian government department or social media company regarding censorship of Australians' social media posts? (Senator Antic)

- Pfizer did not have any conversations with government or social media companies regarding censorship of social media posts.

Regarding the Doherty Institute modelling, was Pfizer consulted by anyone working on this report in assembling the modelling particularly whether Pfizer provided any advice on the vaccine's efficacy against transmission? (Senator Canavan)

- Pfizer was not consulted on the Doherty Institute report. Pfizer was not involved in the development of any government vaccine mandates.