Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D22-5167274

[redacted]
By email: [redacted]

Dear [redacted],

FREEDOM OF INFORMATION REQUEST FOI 3604
Notice of Decision

1. I refer to your request dated 5 February 2022 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

> *"the following documents relating to the provisional approval of the Pfizer-BionTech BNT162b2 vaccine in January 2021:*
> 1. *"All documents relating to the TGA's assessment of the risk of and/or presence of **micro-RNA sequences (miRNA)** comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence).*
> 2. *All documents relating to the TGA's assessment of the risk of and/or presence of **Oncomirs** (oncogenic miRNA - microRNA) comprised within the Comirnaty mRNA active ingredient (mRNA genomic sequence).*
> 3. *All documents relating to the TGA's assessment of the risk of and/or presence of **Stop Codon read-through** (suppression of stop codon activity) arising as a result of the use of pseudouridine in the Comirnaty miRNA active ingredient (mRNA genomic sequence).*
> 4. *Any document showing that the TGA has assessed the composition of the **final protein product** (molecular weight and amino acid sequence) produced following injection of the Comirnaty mRNA product in human subjects.*
> 5. *All documents relating to the TGA's assessment of the risk of the use of the **AES-mtRNR1 3' untranslated region** of the Comirnaty mRNA product in human subjects."*

Decision Maker

2. I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

3. Unfortunately, I am unable to continue to process your request because the documents you have requested do not exist.

4. By way of background, I wish to advise you that the Pfizer Comirnaty vaccine has been provisionally approved by the TGA for use in individuals aged 12 years and over; for use in individuals aged 5-11 years; and as a booster dose for individuals aged 16 years and over. The provisional approval pathway balances the benefits of early access with the uncertainties inherent to the fact that additional data are required. This pathway is available for other prescription medicines, not just vaccines. Further details of the

provisional approval pathway are available at: www.tga.gov.au/provisional-approval-pathway-prescription-medicines

5. Before a COVID-19 vaccine can be provisionally approved in Australia, the TGA must establish the acceptable safety, quality and efficacy of the vaccine based on a comprehensive evaluation of a wide range of information. This includes clinical studies, non-clinical and toxicological studies, chemistry, risk management and manufacturing information. The pivotal clinical trials supporting the safety and effectiveness of vaccines in the provisionally approved age groups have been peer-reviewed, published in reputable medical journals and are publicly available.

6. A large team of clinical and scientific experts at the TGA carefully review this data and seek advice from the Advisory Committee on Vaccines (**ACV**), an independent clinical expert committee, prior to a senior medical officer making a regulatory decision. Even though this is an expedited process, no element of the evaluation is rushed, and no data or specific safety concerns (such as oncogenic activity) are overlooked. A vaccine is only provisionally approved by the TGA if this rigorous process is completed, and the benefits are considered to be much greater than any potential risks. As part of the provisional approval, sponsors are also required to continue to submit evidence of longer-term safety and efficacy to the TGA.

7. There was no evidence of any concerns relating to "*microRNA*", "*oncogenic miRNA*", "*suppression of stop codon activity*", the "*final protein product*" or "*AES-mtRNR1 3' untranslated region*" identified during the provisional approval process. As such there are no documents falling within the scope of your request. Please be assured that if any relevant safety concerns were identified as possible or likely, they would be investigated thoroughly.

8. The TGA has published a range of regulatory documents relating to the provisional approval of each COVID-19 vaccine, which provides detailed information regarding the evaluation process and the data that were considered. These include the Australian Public Assessment Report (**AusPAR**), the Product Information (**PI**) and the Consumer Medicine Information (**CMI**), and they are available at: www.tga.gov.au/covid-19-vaccines.

9. In addition, the TGA, like other regulatory agencies around the world, continues to monitor the safety of vaccines and medicines after they are approved to contribute to a better understanding of their safety profile. General information about the safety of medicines and how the TGA monitors safety is available here: https://www.tga.gov.au/medicines-safety.
   The existing safety monitoring system for vaccines involves:
   - reviewing and analysing reports of suspected side effects (also known as adverse events) submitted by health professionals and consumers.
   - requiring pharmaceutical companies to have risk management plans for the vaccines they supply.
   - proactively reviewing medical literature and other potential sources of new safety information.
   - working with international regulators to assess significant side effects detected overseas.
   - working with State and Territory health departments and clinical experts to ensure a coordinated approach.

10. Pharmaceutical companies also have legal obligations to monitor, collect, manage and report on safety data, known collectively as their 'pharmacovigilance responsibilities'.

11. Prior to the COVID-19 vaccine rollout, the TGA implemented a number of enhancements to strengthen the existing vaccine safety monitoring system, to allow for early detection and investigation of possible safety issues associated with COVID-19 vaccines, and rapid communication of any confirmed safety issues. These enhancements are described in the COVID-19 vaccine safety monitoring plan, published on the TGA website at: www.tga.gov.au/resource/covid-19-vaccine-safety-monitoring-plan.

12. Adverse event reporting data provides a source from which to detect patterns of events that indicate a possible safety issue, or 'safety signals.' The TGA conducts regular statistical analyses of adverse event data to detect signals, in addition to closely monitoring the occurrence of 'adverse events of special interest'. Investigation of safety signals may involve activities such as more detailed analysis and review of adverse event report data, consideration of published literature or information from medicines regulators in other countries, and review of safety data from international use of the vaccine provided by the vaccine sponsor.

13. This provides confidence that any safety issues will be identified promptly, including any safety issues regarding "*microRNA"*, "*oncogenic miRNA*", "*suppression of stop codon activity*", the "*final protein product*" or "*AES-mtRNR1 3' untranslated region"*.

14. If our monitoring confirms a safety issue, we take prompt action to make this information available to health professionals and the public. Each week, the TGA publishes the outcomes of our ongoing monitoring and safety investigations of the COVID-19 vaccines available at: www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report.

15. I also wish to advise you that the TGA ensures there is an independent quality assessment of every batch of vaccine supplied in Australia, to ensure vaccines meet quality standards prior to being released for use. Tests are performed on a variety of the vaccine's properties, including assessments for composition, identity, potency, purity and adventitious agents (contamination with microorganisms). The testing results, along with the review of the manufacturing documentation for each batch, provides assurance that the vaccine being supplied is in line with registered products on the Australian Register of Therapeutic Goods (**ARTG**).

16. Further information on the batch assessment process, along with the test results for each batch of COVID-19 vaccine that has been tested by the TGA, is publicly available here: https://www.tga.gov.au/batch-release-assessment-covid-19-vaccines.

17. In addition to the vaccine safety monitoring conducted by the TGA, AusVaxSafety, which is led by the NCIRS and funded by the Australian Government Department of Health, conducts active vaccine safety surveillance of the COVID-19 vaccines in use in Australia to ensure their ongoing safety. This information is updated regularly and is accessible here: https://www.ausvaxsafety.org.au/safety-data/covid-19-vaccines.

18. AusVaxSafety has published articles explaining how current data gives us confidence about the long-term safety of COVID-19 vaccines and how the TGA monitors side effects. If you would like to learn more, we refer you to: https://www.ausvaxsafety.org.au/how-do-we-know-covid-vaccine-wont-have-long-term-side-effects.

19. As the TGA holds no documents fallen within the scope of your FOI request, I am notifying you of my decision to refuse your request for access under section 24A of the FOI Act.

Reasons for Decision

20. The reasons for my decision are set out above. Despite a thorough and complete search, the documents you have requested do not exist. In these circumstances, section 24A of the FOI Act states that an agency is able to refuse (discontinue processing) the request. Specifically, the FOI Act states:

    requests may be refused if all reasonable steps have been taken to find a document and the document does not exist.

21. Please be assured that the TGA's electronic databases, files and corporate file lists have been searched and following these searches I am satisfied that all reasonable steps have been taken to find the documents requested. However, the documents you have requested do not exist.

Review and Complaint Rights

22. If you are not satisfied with this decision, you can either seek internal review or apply to the OAIC for review of the decision. Further information can be found on the OAIC website at the following link: www.oaic.gov.au/freedom-of-information/reviews-and-complaints/

23. If you have any queries regarding this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

Dr Lisa Kerr, PhD MBA
Assistant Secretary, Laboratories Branch
Medical Devices and Product Quality Division
Therapeutic Goods Administration
18 February 2022