Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D22-5204642

Mr Jimmy Recard
By email: foi+request-8463-3dfac206@righttoknow.org.au

Dear Mr Recard,

FREEDOM OF INFORMATION REQUEST FOI 3634
Notice of Decision

1. I refer to your request dated 18 February 2022 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

> *"Pursuant to the Freedom of Information Act 1982, I seek access to the safety signal investigation documents you hold that contain both the term "brain fog" and the word "Comirnaty".*
> *It is noted from previous FOI requests that the number of documents held by the TGA that contain both the term "brain fog" and the word "Comirnaty" is in excess of 289 documents. (FOI request 3478).*
> *It is also noted that correspondence between the Department of Health and international regulators, territory health departments, pharmaceutical companies and/or State and Territory health departments and clinical experts that contain both the term "brain fog" and the word "Comirnaty" exceed 15,072 pages. (FOI request 3603).*
> *I make this request as a matter of public interest and draw the respondent's attention to Section 11b of the Freedom of Information Act 1982.*
> *I put the Department of Health on notice should it refuse my request to these documents I will seek access through the Federal Court of Australia."*

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. Although, as outlined in previous correspondence to you, the TGA has received reports of "brain fog" following vaccination with the Pfizer Comirnaty vaccine, the TGA's comprehensive safety monitoring system described above has not identified any relevant safety signals. As such, there are no documents falling within the scope of your request for "safety signal investigation documents you hold that contain both the term "brain fog" and the word "Comirnaty". Please be assured that if any relevant safety concerns were identified through our comprehensive safety monitoring, they would be investigated thoroughly.

4. By way of background, the TGA continuously monitors the safety of all medicines in use in Australia. If our monitoring confirms a safety issue, we take prompt action to make this information available to health professionals and the public. General information

about the safety of medicines and how the TGA monitors safety is available here: https://www.tga.gov.au/medicines-safety.

5. 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.

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

7. 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.

8. All adverse event reports submitted to the TGA are evaluated, duplicate reports are rejected, and the information contained therein is uploaded to the Database of Adverse Event Notifications (**DAEN**). You can search the DAEN for "COVID" in the medicines report section, available here: https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx. Select the medicines you want to search for by ticking or unticking the boxes. For example, to conduct a search by active ingredient, tick the box for each trade name containing the active ingredient.

9. I particularly wish to advise you that you can filter adverse event reports for a medicine by date or adverse event type (MedDRA reaction term). This allows you to identify reports which may be of particular interest to you. For example, listed MedDRA reaction terms under the MedDRA system organ class "Psychiatric disorder" include "Confusional state".

10. There are two types of results shown in two tabs: medicine summary and list of reports. In the "list of reports" tab when you search for the COVID-19 vaccine, the results table provides the case number, report entry date, the age of the person, gender, medicines reported as being taken and the reaction.

11. Reporting of an adverse event and publication of an adverse event in the DAEN does not mean the event was related to the relevant medicine. There might be no relationship between the adverse event and the medicine - it may be a coincidence that the adverse event occurred when the medicine was taken, and the symptom may be related to an underlying illness or to other factors. Expert analysis and review of adverse event reports is needed to determine whether there may be a link between reported events and medicines. If you wish to see further information on the TGA's guide to adverse events reporting, you may wish to consider the following: https://www.tga.gov.au/adverse-event-reporting.

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. The value of a system such as this is that it allows for detection of possible safety issues from real-world use of the vaccines by facilitating reporting of events even where detailed information required for an individual causality assessment (such as information about a patient's medical history or test results) is not available. As a result, the TGA is able to capture a large number of adverse event reports for analysis (the TGA has received over 109,000 adverse event reports for COVID-19 vaccines), and to identify specific cases in which more detailed information is required from reporters to contribute to signal detection or investigation.

14. This provides confidence that any safety issues will be identified promptly, including any safety issues regarding "*brain fog"* and the Pfizer Comirnaty vaccine.

15. 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.

16. The TGA has also published range of regulatory documents relating to the provisional approval of each COVID-19 vaccine, including 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. The PI is the key source of information for health professionals as it provides a summary of the scientific information relevant to the safe and effective use of a prescription medicine. The PI includes information on adverse events which were observed in clinical trials, as well as those observed from post-market surveillance. The TGA works with sponsors to ensure the PI remains up to date and can mandate updates to the safety information included in the PI.

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

Elspeth Kay
Assistant Secretary,
Pharmacovigilance Branch
Medicines Regulation Division
Therapeutic Goods Administration
8 March 2022