Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-344632

Mr Jimmy Recard

**By email: foi+request-8197-c3a9d991@righttoknow.org.au**

Dear Mr Recard,

**FREEDOM OF INFORMATION REQUEST FOI 3478**
**Request Consultation Process**

1. I refer to your request dated 14 December 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) in which you make the following request:

> *"Pursuant to the Freedom of Information Act 1982, I seek access to all the documents you hold that contain both the term "brain fog" and the word "Comirnaty"*

**Decision Maker**

2. I am the Therapeutic Goods Administration (**TGA**) officer authorised to make a decision on your request under the FOI Act.

**Request too voluminous to process**

3. The TGA has now undertaken a preliminary search and retrieval for documents coming within the scope of your request. As a result, TGA officers have identified in excess of 289 relevant documents, including individual adverse event reports, that would have to be processed for your request to be finalised.

4. Additionally, your request for "*all the documents you hold that contain both the term "brain fog" and the word "Comirnaty*", does not enable TGA officers to identify all specific documents relevant to your request. Therefore, in order to satisfy your request, TGA officers would be required to retrieve all documents held by the agency related to the Comirnaty vaccine and undertake searches for the keywords specified in your request. To do so would amount to a substantial and unreasonable diversion of the TGA's resources. As your request has already been found to be too voluminous to process (based on the 289 documents already identified), the TGA has not continued processing your request.

5. Under paragraph 24(1)(a) of the FOI Act, I as a decision maker must consult you if I am satisfied that a "practical refusal reason" exists in relation to your request. A practical refusal reason exists if the work involved in processing the request would substantially and unreasonably divert the resources of the TGA from its other operations.

6. A copy of the sections of the FOI Act that set out the consultation process (sections 24, 24AA and 24AB) is at **Attachment A.**

7. In deciding whether the processing of your request would involve a substantial and unreasonable diversion of resources such that a practical refusal reason exists, I am entitled under section 24AA(2) of the FOI Act to consider the resources that would have to be used in the following activities:

    - identifying, locating and collating the documents;
    - deciding whether to grant or refuse access to each document and/or to provide an edited copy which would include examining each document and consulting with any person (including those that I would be required to consult under the FOI Act);
    - making a copy or edited copy of each document; and
    - notifying any interim or final decision on the request (including to any third party consulted in the event that a decision is made to give access to the document).

8. In coming to a view that a practical refusal reason exists in relation to your request I have had regard to the following:

    - the correspondence from you of 14 December 2021, including the terms of the FOI request,
    - the estimated volume of documents involved and the work involved in processing them - preliminary estimates from the relevant line areas of the TGA identified at least 289 documents;
    - as discussed above, there are additional areas where searches have not been completed which are likely to have additional relevant documents and therefore the total number of relevant documents is likely to be higher than the estimate;
    - the need to prepare a schedule detailing all relevant documents;
    - the fact that each of those documents contain personal information in relation to which consideration would need to be given about whether an exemption should be claimed and whether consultation with third parties is required and if so, preparation of schedules for the third party detailing all relevant documents;
    - the assumption that a substantial number of those documents may be capable of being made available (even if in edited form with exempt material redacted), the time taken to appropriately edit each document and to make copies;
    - the fact that any decision letter would need to list each document in an attachment setting out the outcome of the consideration of whether exemptions apply; and
    - the need to prepare at least 289 third party decision letters and associated schedules, should any third parties object to the proposed release of their information.

9. Based on my conclusion that the processing of your request could take approximately 884 hours, I consider your request to be an unreasonable diversion of the TGA's resources to process in its current form.

**Requirement to undertake a request consultation process**

10. Under subsection 24(1) of the FOI Act, I, as a decision maker must consult you if I am satisfied that a "practical refusal reason" exists in relation to your request. A practical refusal reason exists if the request does not satisfy the requirement in paragraph 15(2)(b) (identification of documents).

11. In coming to a view that a practical refusal reason exists in relation to your request, I have had regard to the following:
    - your request dated 14 December 2021;
    - the relevant sections of the FOI Act, being:
        - section 15(2)(b),
        - section 24(1), and
        - section 24AA(1)(b)
    - the volume of documents held by the TGA regarding 'Cominarty' and 'brain fog';
    - the amount of third parties that would need to be consulted which the TGA estimates to be in excess of 289;
    - the amount of time it would take TGA officers to extract and search each of the aforementioned documents for your specified search terms; and
    - the volume of relevant information already in the public domain

12. I also find that the work involved in processing this request would be an unreasonable diversion of the TGA's resources, as advice on the data and sensitivity of the information in these documents would need to be provided by specialised technical staff at the TGA (i.e., senior medical officers, nurses, pharmacists and scientists) a majority of whom are presently engaged in analysis of adverse event data and investigation of safety issues relating to COVID-19 vaccines. The analysis and investigation of medicine and vaccine safety issues, and associated regulatory actions, are of significant public health impact. As you would appreciate, if these officers are required to consider large FOI requests, this diverts their time and attention from undertaking their primary role as evaluators.

13. In addition, the administrative teams providing critical support to the TGA's evaluators and the other safety monitoring business of the TGA, and the FOI team which is also currently dealing with a high volume of COVID-19 related FOI requests. Processing your request would engage resources of those teams that would otherwise be supporting the broader operations of the TGA's safety monitoring business and processing other FOI requests. In this regard, the FOI Guidelines states that a relevant matter in deciding a practical refusal reason exists is "the impact that processing a request may have on other work in the agency or minister's office, **including FOI processing (emphasis mine)** (see paragraph 3.117 of the FOI Guidelines).

14. Paragraph 3.117 of the FOI Guidelines indicates another matter I may take into account in deciding whether a practical refusal reason exists is whether there is a significant public interest in the documents requested and what information is published. I consider that there is a public interest in evidence supporting the safety of COVID-19 vaccines that are administered in Australia. To a very large degree, that information is publicly available.

15. The TGA has published a range of regulatory documents relating to the provisional approval of each COVID-19 vaccine. 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. These documents provide detailed information regarding the evaluation process for each vaccine and the data considered in establishing the acceptable safety, quality and efficacy of the vaccine.

16. The TGA continuously monitors the safety of all medicines in use in Australia. This information is largely published on the Database of Adverse Event Notifications (**DAEN**). The DAEN contains information on adverse events reported following administration of a medicine, including the COVID-19 vaccines. As at 19 August 2021, the TGA has reduced the time between adverse event reports being accepted into our database and published on the DAEN from 90 days to 14 days. This decision was made in response to the strong public interest in adverse event reports relating to COVID-19 vaccinations and allows reports for vaccines publicly available more quickly.

17. To expand on that process further, I wish to advise that the TGA's existing safety monitoring system for vaccines involves:
    - reviewing and analysing reports of suspected side effects (also known as adverse events) submitted by health professionals, consumers, state and territory health departments and pharmaceutical companies.
    - 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.
    - Pharmaceutical companies also have legal obligations to monitor, collect, manage and report on safety data, known collectively as their 'pharmacovigilance responsibilities'.

18. All adverse event reports submitted to the TGA are evaluated, duplicate reports are rejected, and the information contained therein is uploaded to the DAEN.

19. You can search the DAEN for "COVID" in the medicines report section, available here: https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx. Once you have typed the first three letters of a medicine name, a list of trade names will appear with the active ingredients shown in brackets. Where the reporter has only provided the TGA with the active ingredient name, the database will display 'Tradename not specified'. Select the medicines you want to search for by ticking or unticking the boxes.

20. You can filter the search results by date. You can also use the 'Advanced search' feature to filter the adverse event results by reaction type, which may assist you in locating information relevant to your request.

21. There are two types of results shown in two tabs: medicine summary (this summary groups reported adverse events together) and list of reports (this lists all relevant reports in chronological order). 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.

22. The TGA analyses adverse event report data and reviews individual reports to identify possible safety issues for investigation. If these investigations confirm a safety signal, the TGA takes appropriate action. 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. 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

23. The TGA also publishes a weekly safety report for COVID-19 vaccines. All weekly safety reports remain available on the TGA website at this address: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report. These weekly reports include information about identified side effects and safety signals associated with the COVID-19 vaccines.

24. 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. The information gathered is updated regularly and is accessible here: https://www.ausvaxsafety.org.au/safety-data/covid-19-vaccines. This includes information about common and notable side effects of the COVID-19 vaccines and their prevalence.

**Notification of request consultation process**

25. I am notifying you of my intention to refuse to give access to the documents that come within the scope of your request.

26. I am satisfied that, because of the number of documents involved in your request, the number of third parties that would need to be consulted, and the number of hours involved in considering exemptions and making a decision on the documents as set out above, your request would substantially and unreasonably divert staff in regulatory areas of the TGA who would be required to review and consider the documents and any submissions provided by third parties on the documents, from the performance of their day-to-day functions.

27. Before deciding to refuse access to documents, I am required under paragraph 24(1)(a) of the FOI Act to undertake a request consultation process in accordance with section 24AB of the FOI Act and provide you with the opportunity to refine the scope of your request.

28. Accordingly, you are now afforded fourteen calendar (14) days from your receipt of this letter in which to contact the TGA to discuss a revision of the scope of your request.

29. Before the end of the 14-day consultation period, you must do one of the following:
    - withdraw your request;
    - make a revised request; or
    - indicate that you do not wish to revise your request.

30. If you have not contacted the TGA within 14 days of receiving this letter to do one of the above or consulted the TGA to discuss revising its scope, your request is taken to have been withdrawn.

31. If you wish to refine the scope of your request you may contact the FOI team on (02) 6289 4630 or at TGAFOI@tga.gov.au.

32. Please note that if you indicate that you do not wish to revise your request or revise your request in such a way that I am still of the view that processing it would substantially and unreasonably divert TGA resources from other operations, I may refuse your request under paragraph 24(1)(b) of the FOI Act.

Yours sincerely

*Signed electronically*

Dr Claire Larter
Director
Pharmacovigilance Branch
Therapeutic Goods Administration
06 January 2022