Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-3324925

Mr Michael Betts

By email: foi+request-8008-e6e10322@righttoknow.org.au

Dear Mr Betts,

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

1. I refer to your query dated 25 October 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) in which you make the following request:

   *"I seek access to all Government held documents, including but not limited to electronic messages, recorded voice calls, memos, dossiers, reports, or advice, that contains the terminology "brain fog", "cognitive", "memory" or "confusion" related to the Comirnaty Pfizer vaccination. "*

2. Following further correspondence from the FOI Team, advising that your request was not considered to be valid under the FOI Act, on 3 November you replied as follows:

   *"I disagree with your decision and request an internal review of my request.*
   *The points of relevance relate to my allegation that the Department of Health is being in possession of documents (inter alia) that contain the terminology "brain fog", "cognitive", "memory" or "confusion" related to the Comirnaty Pfizer vaccination"*
   *Since this information concerns public health (including mine) I say that I and the Australian People have a right to access this information.*
   *Document word searches are simple methods to extract these data.*
   *Seeking such documents from Ministerial Offices which encompass my request have not been actioned and as such, I reserve my right to make complaint with the Office of the Australian Information Commissioner and/or seek Order of the Federal Circuit Court of Australia."*

**Decision Maker**

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

**Request does not meet the formal requirements under the FOI Act**

4. As stated in the TGA's correspondence to you on 2 November 2021, your query is not a valid FOI request under the FOI Act as it does not meet the formal requirements set out in paragraph 15(2)(b) of the Act.

5. For the purposes of section 24 of the FOI Act, an agency or minister may decide that a practical refusal reason exists in relation to a request if the request does not satisfy the requirement in

paragraph 15(2)(b) (Section 24AA(1)(b)). I am now writing to inform you of my intention to refuse your request on the basis that a practical refusal reason exists.

6. Under section 24AB of the FOI Act, the TGA is required to allow an applicant a reasonable opportunity to revise a request before it is refused for a practical refusal reason.

**Reasons for decision**

7. Paragraph 15(2)(b) of the FOI Act states that in order for a request to be valid, the request must provide such information as is reasonably necessary to enable a responsible officer of the agency or the minister to identify the document that is requested.

8. Your request for "*all Government held documents, including but not limited to electronic messages, recorded voice calls, memos, dossiers, reports, or advice, that contains the terminology "brain fog", "cognitive", "memory" or "confusion" related to the Comirnaty Pfizer vaccination*", does not enable TGA officers to identify 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.

9. For example, the documents initially provided by Pfizer for the provisional registration of the Pfizer (Comirnaty) vaccine included 158 documents containing at least 34,958 pages. This is only one component of the documents provided by Pfizer related to the Pfizer (Comirnaty) vaccine and does not include additional documents such as those for the extension of indication for use in individuals 12 - 15 years and older. Therefore, all documents held by the TGA would be significantly larger than this figure and would be too voluminous to process, particularly if the TGA was required to locate documents relating to Pfizer's COVID-19 vaccine and to subsequently search the documents for the keywords you have specified.

**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 25 October 2021, and subsequent correspondence on 3 November 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 the Comirnaty vaccine,
    - 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. A copy of the sections of the FOI Act that set out the consultation process (sections 24, 24AA and 24AB) is at **Attachment A**. 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 required under subsection 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 relevant 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 documents despite the objections of the relevant third party).

13. I consider that the number of documents which may potentially fall within the scope of your request (being all documents held by the TGA relating to the Comirnaty vaccine), in addition to the necessary consequential work associated with considering whether the documents may be lawfully disclosed, would have a substantial effect on the operations of the TGA.

14. I also find that the work involved in processing this request would be an unreasonable diversion of the TGA's resources, including interrupting TGA officers engaged in evaluation and assessment of prescription medicines, including vaccines. As to the critical work that these officers perform, I note that evaluation and assessment of applications for registration for vaccines and other prescription medicines are required to be finalised within strict statutory timeframes. TGA's officers are also engaged in safety monitoring of medicines and 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.

15. In addition, the administrative team providing critical support to the TGA's evaluators and the other prescription medicine business of the TGA and the FOI team are 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 evaluators, the broader operations of the TGA's prescription medicine 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).

16. I also note that there are likely to be significant charges imposed on you for processing your request (as calculated in accordance with the *Schedule to the Freedom of Information (Charges) Regulations 2019*) based on the number of documents potentially captured by the scope of your request.

17. 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 and has been provided to you in previous correspondence.

18. For example, on 2 November 2021 you were provided links to the 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.

19. We also provided you with information regarding adverse event reporting and monitoring and how to access the Database of Adverse Event Notifications – medicines (**DAEN**). 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 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.
    - Pharmaceutical companies also have legal obligations to monitor, collect, manage and report on safety data, known collectively as their 'pharmacovigilance responsibilities'.

20. As previously described, all reports submitted to the TGA are evaluated, duplicate reports are rejected, and the information contained therein is uploaded to the DAEN. The DAEN contains information on all adverse events reported following administration of a medicine, including the COVID-19 vaccines.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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**

27. I am notifying you of my intention to refuse your request on the basis that it does not meet the formal requirements of section 15(2) of the FOI Act.

28. Before deciding to refuse your request, 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 so that the TGA may begin to process it.

29. Accordingly, you are now afforded fourteen (14) calendar days from your receipt of this letter in which to contact the TGA to discuss a revision of the scope of your request. Please note that these are suggestions only and do not guarantee the practical refusal reason will no longer exist.

30. You may wish to consider the following suggestions to revise the scope of your request:
    - specifying documents created within a certain date range (for instance, 1 August 2021 – 1 October 2021), or
    - specifying kinds of documents (for instance, clinical study reports, adverse event reports), or

    specifying documents created by a particular entity, (for example, the TGA or a third party company).

31. 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.

32. Should you choose to revise your request, section 15(5)(b) of the FOI Act provides that the processing period commences on the day after the day the agency or minister is taken to have received a request that meets the formal requirements of sections 15(2) and (2A) of the FOI Act.

33. The TGA is then required to take all reasonable steps to notify you of a decision on the request no later than 30 days after your request becomes valid (s 15(5)(b)).

34. 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.

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

36. 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,

*Authorised and electronically signed by*

Dr Grant Pegg
Assistant Secretary
Prescription Medicines Authorisation Branch
Medicines Regulation Division
Therapeutic Goods Administration
Department of Health
16 November 2021