Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D22-5161101

Mr Jimmy Recard
By Email: foi+request-8347-86d48ba7@righttoknow.org.au

Dear Mr Recard,

FREEDOM OF INFORMATION REQUEST FOI 3603
Request Consultation Process

1. I refer to your request dated 31 January 2022 under the *Freedom of Information Act 1982* (**the FOI Act**) in which you sought access to the following documents:

> *"1. In regards to correspondence between the Department of Health and*
> *a) "international regulators" and/or*
> *b) "territory health departments and/or*
> *c) "pharmaceutical companies" and/or*
> *d) " State and Territory health departments and clinical experts"*
> *that contain both the term "brain fog" and the word "Comirnaty"*
> *2. In regards to the medical literature and other potential sources of new safety information in relation to the side effect of "brain fog" and "Comirnaty".*
> *3. that is known as the "risk management plan" of Comirnaty Covid-19 vaccination.*
> *4. Any internal memo's between the TGA and the Australian Federal Minister of Health that include the term "Brain Fog" and "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 falling within the scope of your request. As a result, I can confirm that the scope of your request is too voluminous to process.

4. Regarding item 1 of your request, preliminary estimates from the relevant line areas of the TGA suggest that the scope of your request includes approximately 312 documents, containing a total of approximately 15,072 pages. Each of these documents contains sensitive health information and will require consultation with third parties, including States and Territories, and the subjects of adverse event reports. As a result, your request is too voluminous to process.

5. I wish to advise you that the TGA does not hold any documents falling within the scope of item 2 or item 4 of your request.

6. Regarding item 3 of your request, I wish to advise you that the TGA holds multiple versions of the Pfizer Comirnaty EU Risk Management Plan (**RMP**) and multiple versions of the Risk Management Plan Australia-Specific Annex (**ASA**). Preliminary estimates suggest that the

scope of item 3 of your request includes 8 documents, containing approximately 1,160 pages. Each of these documents contains commercially valuable information. These documents will require consultation with third parties, including the pharmaceutical sponsor. As a result, your request is too voluminous to process.

7. However, I am pleased to advise you that the EU RMP has been published online by the European Medical Agency. The TGA has also published the ASA in response to a previous FOI request. As such, the documents you are seeking in item 3 are publicly available. Further information and guidance on accessing these documents is provided below.

8. Given the scope of documents falling under your request, I am of the view that your request is too voluminous to process.

Requirement to undertake a request consultation process

9. 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. As mentioned above, I am of the view that a practical refusal reason exists in relation to your request.

10. 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 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 documents despite the objections of the relevant third party).

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 31 January 2022.
    - the estimated volume of documents involved, and the work involved in processing them, for example, approximately 320 documents containing approximately 16,232 pages.
    - Each of the documents relevant to Item 3 of your request may contain commercially valuable information, that is likely to have a commercial value to the sponsor that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed. Consideration would need to be given to whether an exemption should be claimed and whether consultation with the relevant third party is required, and, if so, preparation of schedules for the third party detailing all relevant documents.
    - in addition, each document relevant to Item 1 of your request is likely to contain personal information, in relation to which consideration would need to be given to whether an exemption should be claimed and whether consultation with the relevant third party is required and, if so, preparation of schedules for the third party detailing all relevant documents.

- this is particularly relevant as the data includes sensitive health information, which may also include coroner's reports that are likely to require consultation with the third parties or the representatives of deceased persons.
- even if personal information were redacted, the individuals concerned may still be reasonably identifiable to their family members, or members of the public, due to the sensitive health information contained in the reports.
- further, as some of these reports may have been reported in the media and on the TGA's website, even with personal information redacted, these persons may still be reasonably identifiable from the remaining information in the reports. Due to my concern that these individuals may still be reasonably identifiable in the documents, even with personal information redacted, the TGA would need to consult with a significant number of third parties.
- the number of affected third parties. The FOI Guidelines provides that there is a requirement to consult with an individual or legal personal representative of a deceased person under section 27 of the FOI Act (see paragraphs 1.27 and 6.161).
- to release this information would likely require the TGA to consult with at least 2 – 3 third parties per document for item 1 of your request, and as such, there is likely to be in excess of 624– 936 third parties.
- the TGA would also be required to consult with additional third parties in relation to documents relevant to item 3 of your request, including the vaccine sponsor. The number of third parties required to be consulted would make this request too onerous to process.
- as you would appreciate, the TGA would need to write to each third party individually, attach copies of their documents, and consider the responses provided and any requested redactions. I would then need to make a decision on these documents, considering these submissions. In addition, if any of the third parties objected to release of documents and I disagreed with them, then I would need to provide them with a decision.
- that 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 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.

12. I consider that the number of pages estimated to fall within the scope of your request and the fact that much of the information is sensitive health information or commercially valuable information, 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.

13. I also find that the work involved in processing this request would be an unreasonable diversion of the TGA's resources. If these officers are required to consider large FOI requests, this diverts their time and attention from undertaking their primary role. In addition, the administrative team providing critical support to the TGA's evaluators and the other safety monitoring 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 medicines 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. 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 third parties.

Guidance on accessing the TGA's publicly available information

15. I note that 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 and efficacy of COVID-19 vaccines that will be used in Australia.

16. To a very large degree, the public interest is met through the publication of regulatory documents along with information on adverse event reports that is publicly available in the Database of Adverse Event Notifications (**DAEN**) and the TGA's weekly safety reports.

17. As noted above, in relation to Item 3, the European Medicines Agency has made the Comirnaty EU RMP available online. You can access these documents at: https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty and the links therein.

18. In addition, the TGA has published the Comirnaty ASA under a previous FOI request. This document is considered in conjunction with the EU RMP. This document is available at: https://www.tga.gov.au/foi-disclosure-log (see FOI 2389, Document 7). Please note, some commercially confidential information has been redacted from this document.

19. 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.

20. You may be particularly interested in the AusPAR for each approval of the Comirnaty vaccine, which contains a summary of the TGA evaluation of the sponsor's RMP.

21. 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.

22. 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'.

23. 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.

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

25. 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

26. 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.

27. 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.

28. Therefore, I consider that insofar as any interest is served by the release of the documents in question, the public interest in evidence supporting the safety and efficacy of COVID-19 vaccines in Australia has already been met through the publication of the supporting regulatory documents and the publicly available materials outlined above.

29. I find that the balance of interests does not favour the expenditure of considerable resources by the TGA. The above diversion of TGA resources would, in my view, be substantial, and is likely to cause serious delays to, and potentially compromise, the TGA's performance of its regulatory functions under the *Therapeutic Goods Act 1989*.

30. Having regard to the importance of the prompt and proper performance of the TGA's regulatory functions, I consider that this diversion of resources would be unreasonable in the circumstances.

Notification of request consultation process

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

32. 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.

33. 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.

34. 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.

35. 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.

36. 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.

37. 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

Elspeth Kay
Assistant Secretary
Pharmacovigilance Branch
Therapeutic Goods Administration
Department of Health
18 February 2022