Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-3244595

Mr Dan Q
By Email: foi+request-7970-a8bff942@righttoknow.org.au

Dear Dan,

FREEDOM OF INFORMATION REQUEST FOI 3232
Notice of Decision

1. I refer to your request dated 17 October 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) for access to the following documents:

   "I am writing to request the reviews the TGA has conducted of reports received of deaths in people vaccinated with COVID-19 vaccines.

   Please note that for the purposes of this request:

   1. I am requesting the reviews the TGA has undertaken of reported deaths of individuals vaccinated with COVID-19 vaccines.

   2. I wish to limit this request to reviews the TGA has conducted of all such deaths that were reported to the TGA between the 1st and 7th of August 2021 (inclusive) of individuals vaccinated with COVID-19 vaccines.

   If no such deaths of this criteria were reported within that date range, then I revise the date range requested to the next earliest date where such death has been reported to and including such deaths reported in the six days from that date.

   3. I am requesting for any personally identifiable information to be redacted, or removed where applicable, to enable the provision of the requested documents."

Decision maker

2. I am the 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. By way of background, the TGA is committed to the transparent and accurate reporting of adverse events. All 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 – medicines (**DAEN**) 14 days after being received. The DAEN contains information on all adverse events reported following administration of a medicine, including the COVID-19 vaccines.

5. Reporting of an adverse event and publication of an adverse event in the DAEN does not mean the event was related to the vaccine. Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or weeks of vaccination. If a person dies within the days to weeks after vaccination, the TGA reviews the case to assess the likelihood that the vaccine contributed to the death. Further information on this process in provided below.

6. Between 1 August 2021 and 7 August 2021, there were 24 adverse event reports for COVID-19 vaccines included on the DAEN where death was a reported outcome. Therefore, in order to process your request for "*the reviews the TGA has undertaken of reported deaths of individuals vaccinated with COVID-19 vaccines*," the TGA would need to process at least 24 documents, each containing a significant number of pages. This figure only includes the adverse event reports and does not include other relevant documents which may be related to "*the reviews the TGA has undertaken".*

7. Given the volume of documents falling under your request, I am of the view that your request is currently too voluminous to process.

Requirement to undertake a request consultation process

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

9. 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).

10. 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 between you and the FOI team, including the terms of your request and subsequent correspondence with you, set out in further detail the background below.
    - the estimated volume of documents involved, and the work involved in processing them, namely, the 24 reports in relation to deaths investigated to determine any causal links to the COVID-19 vaccine. The total number of pages is estimated at 480 pages (at a conservative estimate of approximately 20 pages for each report). This is a particularly conservative estimate noting that some

reports may have more than 50 pages, where they include coroner's reports and correspondence with reporters.

- the fact that each report 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 these deaths 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 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 1-2 third parties per report, i.e. there is likely to be in excess of 24 third parties. In these circumstances, affected third parties may also include the reporters, family members of deceased persons and the relevant health professional, which may include coroners, who were involved in considering any causal link between the COVID-19 vaccine and the death. 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.

11. I consider that the number of pages estimated to fall within the scope of your request, the fact that much of the information is sensitive health information, combined with the number of third parties, and 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.

12. I find that the work involved in processing this request would be an unreasonable diversion of the TGA's resources, including TGA's officers engaged in safety monitoring of medicines and vaccines. As to the critical work that these officers perform, I note that 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 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 tie up resources of those teams that would otherwise be involved in supporting evaluators, the broader operations of the TGA's medicines safety monitoring business and processing other FOI requests. In this regard, the FOI Guidelines state that a relevant matter in deciding whether 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 (my emphasis)** (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 information on adverse event reports that is publicly available in the DAEN and the TGA's weekly safety reports.

17. By way of background, you can access information about all adverse events reported following vaccination with the COVID-19 vaccines in Australia via the DAEN, available on the TGA website. The DAEN contains information from reports of adverse events that the TGA has received in relation to medicines, including vaccines, used in Australia. If you are interested in this information, we refer you to: https://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx.

18. Reporting of an adverse event and publication of an adverse event in the DAEN does not mean the event was related to the vaccine. There might be no relationship between the adverse event and the medicine or vaccine - it may be a coincidence that the adverse event occurred when the medicine or vaccine was taken, and the symptom may be related to the 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 vaccination.

19. 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. Large scale vaccination means that coincidentally some people will experience a new illness or die within a few days or

weeks of vaccination. The TGA reviews all deaths reported in people who have been vaccinated. As the number of vaccinated people has increased, so has reporting of fatal events with a coincidental association with vaccination. This does not indicate a link between vaccination and the fatalities reported.

20. If a person dies within the days to weeks after vaccination, the TGA reviews the case to assess the likelihood that the vaccine contributed to the death. This may involve collecting further information about the person, including their medical history, risk factors, any medications they are prescribed, details and timing of the vaccine, hospitalisation records, and any laboratory test results.

21. This will usually involve liaising with the person's GP, specialists and the hospital. In some instances, states and territories convene an expert panel of doctors. These panels often include the treating doctor, discuss the case in detail, and may advise extra tests that may help them understand the event. Outcomes are then provided to the TGA. In such cases, the TGA further reviews the case and decides whether the further independent review is needed.

22. This information is included in a weekly safety report for COVID-19 vaccines published on the TGA website. Any deaths causally linked to any of the COVID-19 vaccines in Australia will be reported on in these updates. 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.

23. This information is also reviewed by other key advisory groups, including the Australian Technical Advisory Group on Immunisation (**ATAGI**) and the government, who monitor the progress of immunisation programs, including for COVID-19. Further information on the ATAGI is available here: https://www.health.gov.au/committees-and-groups/australian-technical-advisory-group-on-immunisation-atagi.

24. The TGA also makes adverse event information available to the public through the DAEN. The DAEN contains information on all adverse events reported following administration of a medicine, including the COVID-19 vaccines. As of 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..

25. 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. For example, to conduct a search by active ingredient, tick the box for each trade name containing the active ingredient.

26. 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. This will provide you with a publicly available list.

27. The public interest in evidence supporting the safety and efficacy of COVID-19 vaccines is also met through the publication of information in the supporting regulatory documents, including the Australian Public Assessment Report (**AusPAR**), the Product Information (**PI**), and the other information that is publicly available in the DAEN and the weekly safety reports. 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, including vaccines. The PI is approved by the TGA, and sponsors must submit an application to the TGA to make any change to the PI. 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 COVID-19 vaccine sponsors to ensure the PI remains up to date and can mandate updates to the safety information included in the PI.

28. The AusPARs and PIs are available for each provisionally approved vaccine here: https://www.tga.gov.au/covid-19-vaccine-provisional-registrations.

29. I consider that insofar as any interest is served by the release of the documents in question, the public interest has already been met through the publication of the supporting regulatory documents, as well as through publication of information regarding deaths and adverse events on the DAEN and the COVID-19 weekly safety reports.

30. 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*. 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 come within the 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 the scope of this request, 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 & Special Access Branch
Therapeutic Goods Administration
28 October 2021