Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-3019760

Mr Daniel Shakespeare
By Email: foi+request-7662-f851018a@righttoknow.org.au

Dear Mr Shakespeare

FREEDOM OF INFORMATION REQUEST FOI 2598

Request Consultation Process

1. I refer to your request dated 6 August 2021 under the Freedom of Information Act 1982 (**the FOI Act**) in which you made the following request:

   "Can I please request the following data pertaining to the stated 425 reports received;

   1. Age and sex of the patient for each report (this data alone cannot be used to identify patients)
   2. The source of each report ie whether the report was made by a practitioner or member of the public."

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 and otherwise publicly available

3. With respect to your request, the TGA does not hold a distinct document which contains the "*age and sex of the patient for each report*" and the "*the source of each report*" for the 425 deaths with temporal links to the COVID-19 vaccines.

4. The TGA is not required under the FOI Act to create documents providing specific information. The information you have requested is contained within numerous reports and other supplementary documents provided to the TGA. To satisfy your request, the TGA would need to identify and consider each report.

5. By way of background, the TGA receives at least one report for each adverse event recorded. It is not uncommon for one adverse event to be reported multiple times, often by both a medical practitioner and representatives for the deceased person. This means that a number of reports are rejected for duplication (for example, there are approximately 115 duplicative reports in addition to the 425 reports you have requested). As you are requesting information relating to the source of all reports, the TGA would need to revisit the duplicative

reports to determine whether the deaths were reported by members of the public, medical practitioners, coroners, or State or Territory health authorities, for example.

6. Therefore, to satisfy your request, the TGA would need to process at least 425 documents and approximately 115 duplicative reports. For this reason, and for reasons explained further below, processing your request would be an unreasonable diversion of the TGA's time and resources.

7. As your request is currently too voluminous to process, the TGA has not continued to process your request.

Requirement to undertake a request consultation

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.

9. 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).

10. 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 6 August 2021.
   - the estimated volume of documents involved, and the work involved in processing them, namely, the 425 reports, plus approximately 115 duplicate reports, in relation to deaths investigated to determine any temporal links to the COVID-19 vaccine. The total number of pages is estimated at 1000 pages.
   - this is also particularly relevant as the data includes sensitive health information that may require consultation with the third parties or the representatives of deceased persons, even with personal information redacted. 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).
   - as you would appreciate, if consultation with third parties is required, 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 taking these submissions into account. Also, 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 clinical 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. Taking into account these matters, I have:
    - considered the time required to undertake the consultation process with at least 425 third parties;
    - considered the time already taken to perform searches for potentially relevant documents; and
    - estimated how long it might take to process the 425 reports containing approximately 1000 pages.

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

13. I also find, for the following reasons, 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.

14. 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 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).

15. 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 and the number of third parties.

Guidance on accessing the TGA's publicly available information

16. 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.

17. To a very large degree, the public interest is 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 Database of Adverse Event Notifications (**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.

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

19. In addition to the PI, the TGA publishes a weekly safety report for COVID-19 vaccines and makes adverse event information available to the public through the DAEN. 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.

20. Notably, the DAEN contains information on the **age and gender** of the patient, as well as the medicines reported as being taken and the reaction. The DAEN can be accessed here: https://apps.tga.gov.au/Prod/daen/daen-entry.aspx.

21. Due to strong public interest of and interest in side effects relating to COVID-19 vaccinations, the TGA has now reduced the time between adverse event reports being accepted into the TGA database and published in the DAEN from 90 days to 14 days. The DAEN reports from 1 January 1971 up to 14 days prior to the date of access. Reports will now be made public prior to in-depth TGA analysis of the data to check for patterns of adverse events that may or may not indicate a safety issue.

22. 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.

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. Similar adverse event data is also made available by international regulators, for example:

- The US Food and Drug Administration's Vaccine Adverse Event Reporting System: https://vaers.hhs.gov/
- The UK Medicines and Healthcare products Regulatory Agency's Yellow Card reporting: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions
- The European Medicines Agency EudraVigilance (European database of suspected adverse drug reaction reports): https://www.adrreports.eu/en/

25. I also note that AusVaxSafety is an active vaccine safety surveillance system that complements the TGA's enhanced safety surveillance activities. Active vaccine safety surveillance uses SMS and a short survey to collect reports of AEFI directly from a subset of people receiving the vaccines. AusVaxSafety is an Australian Government-funded system that shares its findings with the TGA to assist safety investigations and responses. Please see details of AusVaxSafety's latest COVID-19 safety data available here: https://www.ausvaxsafety.org.au/safety-data/covid-19-vaccines

26. 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, as well as through publication of information regarding deaths and adverse events on the DAEN and the COVID-19 weekly safety reports. The changes to the release of the DAEN-level data to the public sooner than the 90-days will further serve to benefit the public interest in this information.

27. 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*.

28. 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

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

30. 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.

31. 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.

32. 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.

33. 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.

34. 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.

35. 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
Acting Assistant Secretary
Pharmacovigilance & Special Access Branch
Therapeutic Goods Administration
27 August 2021