Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D22-5015669

A Long Standing Member of a Religious Community in Western Australia
Email: foi+request-8174-a790b3ce@righttoknow.org.au

Dear Sir/Madam,

FREEDOM OF INFORMATION REQUEST FOI 3509
Request Consultation Process

1. I refer to your request dated 11 December 2021 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

   "Please have the raw data and current reports, or information for COVID 19 vaccines:

   2020 Surveillance of adverse events following immunization in Australia

   2021 Surveillance of adverse events following immunization in Australia"

2. The TGA has split your request into three items, as follows:
   - **Item 1:** 'raw data for COVID 19 vaccines' for 2020 and 2021 surveillance of adverse events following immunization in Australia;
   - **Item 2:** 'current reports for COVID 19 vaccines' for 2020 and 2021 surveillance of adverse events following immunization in Australia; and
   - **Item 3:** 'information for COVID 19 vaccines' for 2020 and 2021 surveillance of adverse events following immunization in Australia.

3. The TGA has interpreted your request for 'raw data' as including all data in the Adverse Event Management System (**AEMS**).

Decision Maker

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

Requirement to undertake a request consultation process

5. 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 indicated that there are over 96,000 adverse event reports, consisting of more than 190,000 relevant pages that would have to be processed for just Item 1 of your request.

6. 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.

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

8. 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).

9. 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 11 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 over 190,000 relevant pages for Item 1 alone;
    - 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 may contain business and/or 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 need to prepare at least 96,000 third party decision letters and associated schedules, should any third parties object to the proposed release of their information;
    - 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; and
    - 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.

10. Based on the number of documents and pages involved, and the number of third parties who I would be required to consult with, I consider your request to be an unreasonable diversion of the TGA's resources to process in its current form.

Reasons for Decision

Too Voluminous to Process

11. With respect to Item 1, your request is too voluminous to process.
12. By way of background, the TGA stores adverse event reports in an internal database, referred to as the AEMS. The information and documents held in the AEMS contain personal information, including sensitive health information, and will require extensive redactions to preserve the personal privacy of patients and adverse event reporters.
13. Processing all the 'raw data' would require processing over 190,000 pages (as a conservative estimate) of reports and associated documents, and involve consulting with over 96,000 third parties.
14. With respect to Items 2 and 3, your request is too voluminous to process.
15. The scope of your request which includes 'current reports' and 'information' is expected to include hundreds of documents as the TGA prepares a variety of reports each week to support our surveillance activities, as well as other reports investigating safety signals. A more precise preliminary search has not been undertaken due to Item 1 having already been identified as too voluminous. These 'current reports' and 'information' are also likely to contain sensitive health information and would also require extensive redactions to preserve the personal privacy of patients and/or adverse event reporters.
16. 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
17. I am satisfied that attempting to collect raw data would substantially and unreasonably divert the TGA (as part of the Department of Health) from its other operations.

Raw Data for Covid-19 Vaccines (Item 1) - Guidance to Publicly Accessible Information

18. While I am not required to direct you to publicly available information, I would like to assist you with your request. I am pleased to inform you that a substantial amount of the information you requested is publicly available through the Database of Adverse Event Notifications (**DAEN**). You can access the DAEN via the TGA website. If you are interested in this information, we refer you to: https://apps.tga.gov.au/PROD/DAEN/daen-entry.aspx. If you wish to obtain information about a specific medicine (including specific COVID-19 vaccine) you can search the name of the medicine in 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. 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.
20. There are two types of results shown in two tabs: medicine summary and list of reports. 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.
21. Reporting of an adverse event and publication of an adverse event in the DAEN 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. Expert analysis and review of adverse event reports is needed to determine whether there may be a link between reported events and medicines. 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.

Current Reports and information (Items 2 and 3) – Guidance to Publicly Accessible Information

22. The TGA publishes a COVID-19 weekly safety report which contains information about adverse events following immunisation. This can be accessed at https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report. However, this initiative only began in 2021 and therefore the information is restricted to that year.

23. As you may know, the Department of Health publishes annual reports on adverse events following immunisation which are available here: https://www1.health.gov.au/internet/main/publishing.nsf/Content/cda-aefi-anrep.htm. I note that the 2020 and 2021 reports have not been released yet. However, AusVaxSafety has published current reports (that is, information from 2020 and 2021) that contain similar information to the Department of Health's annual reports. This data is sorted into different vaccine type including Pfizer, AstraZeneca and Moderna. You can access this information via: https://ausvaxsafety.org.au/covid-19-vaccines-new/all-participants. This page is regularly updated with the most 'current reports'.

24. The TGA has published a range of regulatory documents relating to the provisional approval of each COVID-19 vaccine. These documents include information on adverse events following immunisation. 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.

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. 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. 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
10 January 2022