Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

TRIM Ref: D22-6222034

Mr John Walker
Email: foi+request-9608-ca0c44d2@righttoknow.org.au

Dear Mr Walker

FREEDOM OF INFORMATION REQUEST FOI 4113
Request Consultation Process

1. I refer to your request dated 24 November 2022 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

   "Pursuant to the Freedom of Information Act 1982 I seek all documents in relation to expert advice from the ACV on COVID-19 vaccine safety activities and issues.

   Furthermore I seek the documents you rely upon to refine processes and statistical methods for analysing observed COVID-19 AEFI rates for detecting safety signals that enable rapid analysis of AEFI rates to detect, confirm or disprove emerging COVID-19 safety signals"

Decision Maker

2. 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

3. 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.
4. A copy of the sections of the FOI Act that set out the consultation process (sections 24, 24AA and 24AB) is at **Attachment A**.
5. 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 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).
6. 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 dated 24 November 2022 including the terms of the FOI request;
- the scope of the request and the fact that I believe it is currently too broad and captures an excessive volume of documents;
- the estimated volume of documents identifiable within scope of your request and the work involved in processing them.
- the need to prepare a schedule detailing any relevant documents;
- the fact that each of the 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; 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.

7. I also consider that the likely necessary consequential work associated with considering whether the documents or parts of the documents may be lawfully disclosed, and which parts, would also have a substantial effect on the operations of the TGA.
8. 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 volume of the documents you have requested.
9. In addition, TGA officers within the Pharmacovigilance Branch 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 undertaking pharmacovigilance activities 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** (see paragraph 3.117 of the FOI Guidelines).
10. I find that the balance of interests does not favour the expenditure of considerable resources by the TGA in completing these searches. I am satisfied that the diversion of resources to provide documents in response to your request is not reasonable.

Notification of request consultation process

11. I am notifying you of my intention to refuse to give access to the documents that come within the scope of your request.
12. I am satisfied that your request would substantially and unreasonably divert staff in regulatory areas of the TGA who would be required to search for all relevant documents, review and consider the documents and any submissions provided by third parties on the documents, from the performance of their day-to-day functions.
13. 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.
14. 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.
15. 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.

Comments and Suggestions

16. Please note that in relation to the second paragraph of your request, the first sentence refers to "statistical analysis to detect potential safety issues". For your information, these methods are only used to flag potential issues. The process of signal investigation is broader than the adverse event data in Australia or internationally and includes broader information such as literature searches.
17. Review the ACV meeting statements since 2020 and in particular, any specific meetings of interest to you. Outcomes from the meetings of the ACV can be found on the TGA website at https://www.tga.gov.au/about-tga/advisory-bodies-and-committees/advisory-committee-vaccines-acv.
18. You may wish to consider the following suggestions to revise the scope of your FOI request (please note that these are suggestions only and do not guarantee the practical refusal reason will no longer exist):
    - Identify specific ACV meetings of interest and request meeting minutes;
    - Refining the second paragraph of your request to specific ACV minutes regarding the proposed plan for adverse event monitoring for the covid-19 vaccines, specifically ACV 16 and 17; and
    - Excluding personal information relating to third parties.
19. If you elect to refine the scope of your request, the TGA may seek your agreement to extend the consultation period by a further period, to allow time to consult the relevant technical area further, in accordance with subsection 24AB(5) of the FOI Act.
20. 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.
21. 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.
22. 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

Electronically signed and authorised by

Dr Catherine Brogan
Principal Medical Adviser
Pharmacovigilance Branch
Therapeutic Goods Administration
15 December 2022