Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Scott Bennett
Right to Know

Email: foi+request-10770-e560e9c1@righttoknow.org.au

Dear Mr Bennett

FREEDOM OF INFORMATION REQUEST FOI 4766
Request Consultation Process

1. I refer to your request dated 18 October 2023 under the *Freedom of Information Act 1982* (the FOI Act) and subsequent correspondence between you and the TGA in which the scope of your request was clarified as being for access to the following documents:

   "Can you please supply the particular assessment data for each batch, including the Composition and strength result, Purity and integrity result, Identity result, Endotoxin result or other measured quality or quantity undertaking in laboratory testing by the TGA (Pathway two) in the first instance and by the OCABR (Pathway 2) in the second case where applicable.

   **https://www.tga.gov.au/products/covid-19/covid-19-vaccines/batch-release-assessment-covid-19-vaccines.*

   Clarification: To be clear my request was for the missing result numbers in the fields of the database headed:
   1. Purity and integrity
   2. Identity
   3. Endotoxin
   4. Composition and strength"

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. Your initial request was for the assessment data for each of the COVID-19 batches listed in the database, some of which has been released in previous FOI requests to the TGA (FOI 3471 and 3390) and are available on our website at: Documents released under Section 11C of the Freedom of Information Act 1982, Jul 2021 - Jun 2022 | Therapeutic Goods Administration (TGA).

4. The TGA FOI Team advised on 23 October 2023 that it is likely that the scope of your initial request would be considered too voluminous to process, based on the number of batches assessed by the TGA, and the number of documents associated with each batch release assessment.

5. In your email to the TGA FOI Team on 23 October 2023, you clarified that the scope of your request was for the specific "results numbers" in the fields of the database referenced in the scope of your request. This database shows whether a batch of COVID-19 vaccines have either passed or failed testing in four different areas.
6. Whilst it is possible for the TGA to create a document under section 17 of the FOI Act with the results you have requested, creating a document would be a substantial and unreasonable diversion of the TGA's resources. This is due to the number of batches you have sought results for (being over 400 batches).
7. Section 17 of the FOI Act allows the TGA to create a document containing the discrete information you have requested if it can retrieve the stored information using a computer or other equipment available to the agency. However, subsection 17(2) of the FOI Act relevantly states that:

   (2) An agency is not required to comply with subsection (1) if compliance would substantially and unreasonably divert the resources of the agency from its other operations.
8. I consider that it is unreasonable for the TGA to create a document because the software used by the TGA cannot generate a table containing only individual test results, and therefore, cannot generate a table with only the relevant results that are used to determine whether a batch has passed or failed for each of the fields.
9. The TGA carries out a range of different tests on each batch of vaccine in order to obtain this data, and data would have to be extracted using multiple search terms unique for the specific tests.
10. To create a document with only the information you have requested, technical staff from the Laboratories Branch at the TGA would be required to manually filter out irrelevant information that does not form part of the scope of your request from what is outputted from the software. This process would be time consuming for the staff in the Laboratories Branch. If the TGA were to create a document with this information (including to filter out all irrelevant material), the document would compromise of over 3,000 lines of data that would need to be individually assessed for relevancy, and then refined into a document that would address your request.
11. Additionally, the documents contain large volumes of commercially valuable information relating to the business affairs of various third parties, which the TGA will be required to consult these parties on the release of such.
12. 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.
13. A copy of the sections of the FOI Act that set out the consultation process (sections 24, 24AA and 24AB) is at **Attachment A**.
14. 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:
    - Creating a document with the data you have requested;
    - 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).

15. 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 18 October 2023, including the terms of the FOI request, and subsequent correspondence with the TGA relating to your request;
    - the need to prepare a schedule detailing the relevant document;
    - the fact that any document made will contain a large volume of sensitive commercial 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. This is particularly relevant as data from the test results will likely reveal commercially sensitive information owned by the sponsors of the vaccines, such as specification limits for the quality attributes for each of the COVID-19 vaccines, which is unique to each vaccine, and is not information which is publicly available. The value of this information can be expected to be destroyed or diminished if the information were disclosed.
    - the number of affected third parties that would need to be consulted, as there are at least four third parties. 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 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., toxicologists, pharmaceutical chemists and senior clinical medical officers);
    - That even if some of the information contained within the document 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; and
    - the need to prepare third party decision letters and associated schedules, should any third parties object to the proposed release of their information.

16. I consider that the time to generate a document with the information that falls within the scope of your request, combined with the fact that much of the information is commercially confidential 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.

17. 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 the Laboratories Branch at the TGA. As to the critical work that these officers perform, I note the important work staff of this branch perform in testing therapeutic goods. 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.

18. The time to review any generated document in detail to determine whether any of the documents or parts of the documents could be characterised as exempt, and then redacting the material, would be a substantial and unreasonable diversion of the TGA's resources.

19. 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. However, information about the test results for each batch of COVID-19 vaccines tested in Australia is published by the TGA on the website you have referenced in the scope of your request. Therefore, I consider that insofar as any interest is served by the release of the documents in question, that interest has already been met through the publication of these documents.

20. I find that the balance of interests does not favour the expenditure of considerable resources by the TGA. I am satisfied that the diversion of resources to provide documents in response to your request is not reasonable.

Notification of request consultation process

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

22. I am satisfied that, because of the number of documents involved in your request, the number of third parties that would need to be consulted, and the number of hours involved in considering exemptions and making a decision on the documents as set out above, your request would substantially and unreasonably divert staff in regulatory areas of the TGA who would be required to review and consider the documents and any submissions provided by third parties on the documents, from the performance of their day-to-day functions.

23. 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.

24. 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.

25. 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.

26. 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/s will no longer exist):

    - requesting the results for only 10 batches (preferably all made by the same manufacturer); or
    - requesting the assessment data for only 3 batches (again, preferably all made by the same manufacturer).

27. Should you require further time to consider submitting a revised scope, you are welcome to request an extension to the consultation period in writing to the TGA, in accordance with subsection 24AB(5) of the FOI Act.

28. 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.

29. If you wish to refine the scope of your request, you may contact the FOI team on (02) 6289 4630 or at TGAFOI@health.gov.au.

30. 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

Dr Scott Craig
A/g Assistant Secretary
Laboratories Branch
Therapeutic Goods Administration
3 November 2023