Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Mr Paul Rekaris
**Email:** paulrekaris@gmail.com

Dear Mr Rekaris

**FREEDOM OF INFORMATION REQUEST FOI 25-0166**
**Notice of Decision**

1. I refer to your request dated 1 April 2025 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:

**Initial scope:**

*'Under the Freedom of Information Act 1982 (the FOI Act), I request access to the following documents:*

*1. Any documents from February 2021 until April 2025 (such as but not limited to emails, reports, data, evaluations, meeting minutes, briefings, and proposals) demonstrating, evidencing, or recording the implementation of the "COVID-19 Vaccine Safety Monitoring Plan" (Version 1.0, February 2021) held by the Therapeutic Goods Administration (TGA), including but not limited to:*

*a) Records of the "ample documentation demonstrating compliance" with the objectives of the COVID-19 Vaccine Safety Monitoring Plan explicitly referenced by Ms. Elspeth Kay, Assistant Secretary, Pharmacovigilance Branch, in her FOI decision letter dated 27 February 2022 (Ref: D22-5201218)*

*b) Documents containing the specific outputs listed in the Plan, including:*

*o "Criteria for COVID-19 vaccine report escalation and clinical review incorporated into the TGA's standard procedures" (as specified on page 7 of the Plan)*

*o "Specific protocols for investigating COVID-19 AEFI reports" (as specified on page 8 of the Plan)*

*o "Refined processes and statistical methods for analysing observed COVID-19 AEFI rates for detecting safety signals" (as specified on page 8 of the Plan)*

*c) Records showing implementation of the following specific commitments from the Plan:*

*o Establishment of "a standing COVID-19 expert advisory committee ready to provide advice on COVID-19 vaccine safety issues" (page 9)*

*o "Processes to enable rapid action in response to any emerging COVID-19 vaccine safety concerns" (page 10)*

*Any briefings, reports, dashboards, or summaries (including drafts) prepared for TGA senior management, the Department Secretary, or the Minister that document or evaluate the implementation or effectiveness of the COVID-19 Vaccine Safety Monitoring Plan between February 2021 and April 2025.'*

**Scope refinement received on 5 May 2025 (following first request consultation):**

*'In light of your practical refusal consultation, I am willing to further refine my request as follows:*

*1. Specific Priority Documents (limited to no more than 20 documents):*

*a) The TGA's documented "Criteria for COVID-19 vaccine report escalation and clinical review incorporated into the TGA's standard procedures" (referenced on page 7 of the COVID-19 Vaccine Safety Monitoring Plan)*
*b) Documentation establishing the "standing COVID-19 expert advisory committee ready to provide advice on COVID-19 vaccine safety issues" (page 9 of the Plan)*
*c) "Specific protocols for investigating COVID-19 AEFI reports" (page 8 of the Plan)*
*d) "Refined processes and statistical methods for analysing observed COVID-19 AEFI rates for detecting safety signals" (page 8 of the Plan)*
*e) "Processes to enable rapid action in response to any emerging COVID-19 vaccine safety concerns" (page 10 of the Plan)*

*2. Representative Sample (limited to 25 additional documents):*

*a) Up to 5 documents pertaining to each of the 5 objectives in the Safety Monitoring Plan*
*b) Documents spanning the period February 2021 to December 2023*
*c) A mix of document types (procedures, reports, briefings)*

*3. Document Index:*

*a) A schedule listing key documents identified (with titles, dates, and brief descriptions)*

*This revised request significantly reduces the processing burden while providing essential documentation to understand how the TGA implemented its Safety Monitoring Plan. It addresses your practical refusal concerns by:*

*- Reducing document volume by approximately 88% (from 399+ to about 45 documents)*
*- Focusing on the most significant implementation documentation*
*- Limiting third-party consultation requirements*
*- Providing a framework for future targeted requests*

*As stated in my original request, I am not seeking personal information about individuals or commercially sensitive information about vaccine manufacturers.'*

**Further scope clarification received on 9 May 2025:**

*'1. Point 2 - Representative Sample*
*I'm happy to clarify this request. Instead of a "representative sample," I would like to request:*

*For each of the 5 objectives in the Safety Monitoring Plan, the 5 most significant documents that demonstrate implementation or operationalisation of that objective spanning the period February 2021 to December 2023*

*By "most significant," I mean documents that best demonstrate how the TGA implemented each objective of the Plan (such as procedure documents, key implementation records, major review documents, or substantial operational protocols)*

*This provides specific parameters needed for your search (25 documents total, with clear criteria for selection) while still capturing substantive information about how the Plan was implemented across all objectives throughout the relevant period.*

*2. Point 3 - Document Index*
*I understand your concerns regarding section 17 of the FOI Act and am willing to remove point 3 from my request.*

*Given your advice that processing point 1 alone would be reasonable and would provide valuable information on the TGA's implementation of the Safety Monitoring Plan, I am prepared to proceed with:*

*Point 1 as originally formulated (the specific priority documents)*
*The modified version of point 2 as clarified above*
*Removal of point 3 entirely*

*This revised scope should address your concerns while still providing meaningful documentation of how the TGA implemented its COVID-19 Vaccine Safety Monitoring Plan.'*

**Scope refinement received on 20 May 2025 (following second request consultation):**

*'I note your concern under section 24(1)(b) that the terms in Point 2 of my revised request might be considered too subjective. After reviewing the FOI Act provisions you provided in Attachment A, I am revising my request to ensure it fully satisfies the requirements of section 15(2)(b) by providing objectively identifiable document criteria.*

*1. I accept your advice that Point 1 is clear and reasonable to process, and am happy to proceed with this component.*

*2. For Point 2, pursuant to the TGA's obligation under section 24AB(3) and (4) to take reasonable steps to assist in revising my request, I have refined it as follows:*
*For each of the 5 objectives in the Safety Monitoring Plan, a total of 6 documents per objective selected as follows:*

*a) Up to 6 of the most recent documents from any of these categories (or similar document types), created between February 2021 and February 2025, that implement or relate to that objective:*

*- Standard Operating Procedures (SOPs) or equivalent procedural documents*
*- Case processing instructions and guidelines*
*- Coding and process updates*
*- Workflow process documents*
*- Protocol documents for investigating safety signals*
*- Processes for regulatory actions addressing safety concerns*
*- Public communication procedures for COVID-19 vaccine safety information*
*- Documentation of collaboration mechanisms with stakeholders*
*- Official procedure documents or similar operational instructions*
*- Internal policy documents or comparable guidance materials*
*- Implementation guidelines or similar directional documents*
*- Operational protocols or comparable procedural guidelines*

*b) If fewer than 6 documents exist in the categories listed in (a) for any objective, then the remaining balance should be made up of any other documents that the TGA has classified or identified as relating to the implementation of that objective, selecting the most recent such documents within the same date range.*

*This revision provides the TGA with objective criteria for document identification as required by section 15(2)(b) of the FOI Act, using standard document classification systems and common document types that should be readily identifiable within the TGA's records management systems. The revision specifies:*

*1. A defined number of documents (6 per objective)*
*2. Objective document categories and types*
*3. A clear date range (February 2021 to February 2025)*
*4. An unambiguous selection method (most recent)*

*I believe this revision fully addresses the concern raised in your letter while enabling the TGA to identify the relevant documents using objective criteria, as required by the FOI Act.'*

**Decision maker**

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

**Decision**

3. I am notifying you of my decision under paragraph 24(1)(b) of the FOI Act to refuse access to the documents that come within the scope of your request.

**Reasons for Decision**

4. I am satisfied that, following a request consultation process undertaken in accordance with section 24AB of the FOI Act, a 'practical refusal reason' within the meaning of section 24AA of the FOI Act still exists.

5. Specifically, the scope of item 2 of your revised request requires the TGA to make a subjective decision on which documents are considered to be in scope.

6. In order to identify the 30 documents that you are requesting access to in item 2 of your revised request, the TGA would be required to consider each of the 5 key objectives of the COVID-19 Vaccine Safety Monitoring Plan, identify all documents created between February 2021 and February 2025 from the 12 categories listed by you that relate to the individual key objective (noting that these have not been previously identified or related to that objective and would therefore require subjective interpretation of the relationship to that objective) and then select the 6 most recent documents from this list.

7. Based on my interpretation of this item, the work involved in attempting to identify potential documents, in addition to processing the documents requested in item 1 of your FOI request, would substantially and unreasonably divert the resources of the TGA from its other operations.

8. The reasons for my decisions are set out in further detail below.

**Background**

9. On 24 April 2025 and 16 May 2025, you were issued with separate request consultation letters as your request did not meet the requirements of section 15(2)(b) of the FOI Act. Specifically, you did not provide the TGA with satisfactory information about the documents you were seeking access to as is reasonably necessary to enable staff at the TGA to identify the documents.

10. In the letters dated 24 April 2025 and 16 May 2025, the TGA notified you that a practical refusal reason existed in relation to your request. As required by paragraph 24(1)(a) of the FOI Act, the TGA undertook a request consultation process in accordance with section 24AB of the FOI Act to provide you with the opportunity to contact a TGA officer to consult them about revising the scope of your request so that the practical refusal request would no longer exist.

11. Specifically, you were informed that you had fourteen (14) days from the date of receipt of the TGA's letter in which to contact the TGA to do one of the following:
    - withdraw your request;
    - make a revised request; or

- indicate that you do not wish to revise your request.

12. In your correspondence of 5 May, 9 May and 20 May 2025 in response to the TGA's letters and correspondence, you revised the scope of your request and provided further clarification of your scope as set out above.

**Material considered in Decision-Making**

13. In making my decision, I have had regard to:

- the terms of your FOI request dated 1 April 2025 and subsequent correspondence of 5 May, 9 May and 20 May 2025;
- the TGA's assessment of the time and resources that would be required to process your request;
- relevant provisions of the FOI Act, including sections 24, 24AA and 24AB;
- the guidelines issued by the Information Commissioner under subsection 93A(1) of the FOI Act that I am required to have regard to under subsection 93A(2) of the FOI Act;
- your responses of 5 May and 9 May 2025 to my initial letter of 24 April 2025;
- your response of 20 May 2025 to my subsequent letter of 16 May 2025;
- information from relevant areas of the TGA concerning the resources required to comply with your request, and the effect of same on the TGA's operations.

**Reasons for Decision**

14. Subsection 24AA(1) of the FOI Act defines when a 'practical refusal reason' will exist in relation to a request. Specifically, that provision states:

> (1) For the purposes of section 24, a ***practical refusal reason*** exists in relation to a request for a document if either (or both) of the following apply:
>  (a) the work involved in processing the request:
>  (i) in the case of an agency – would substantially and unreasonably divert the resources of the agency from its other operations; or
>  (ii) in the case of a Minister – would substantially and unreasonably interfere with the performance of the Minister's functions;
>  (b) the request does not satisfy the requirement in paragraph 15(2)(b) (identification of documents).

15. Subsection 24AA(2) of the FOI Act sets out the matters to which I must have regard in deciding whether a practical refusal reason exists. Specifically, it states:

> (2) Subject to subsection (3), but without limiting the matters to which the agency or Minister may have regard, in deciding whether a practical refusal reason exists, the agency or Minister must have regard to the resources that would have to be used for the following:
>
> (a) identifying, locating or collating the documents within the filing system of the agency, or the office of the Minister;
>
> (b) deciding whether to grant, refuse or defer access to a document to which the request relates, or to grant access to an edited copy of such a document, including resources that would have to be used for:
>
> (iii) examining the document; or
>
> (iv) consulting with any person or body in relation to the request;
>
> (c) making a copy, or an edited copy, of the document;
>
> (d) modifying any interim or final decision on the request.

16. Subsection 24AA(3) of the FOI Act also sets out the matters to which I must not have regard to:

    (3) In deciding whether a practical refusal reason exists, an agency or Minister must not have regard to:

    (a) any reasons that the applicant gives for requesting access; or

    (b) the agency's or Minister's belief as to what the applicant's reasons are for requesting access; or

    (c) any maximum amount, specified in the regulations, payable as a charge for processing a request of that kind.

17. I confirm that I have not had regard to any of the matters set out in subsection 24AA(3) in coming to my decision.

18. As noted above, I do not believe your request has sufficiently met the requirements of section 15(2)(b) of the FOI Act. Specifically, item 2 of your request requires the TGA to make a subjective decision on which documents are considered to be in scope.

19. Specifically, staff from the Pharmacovigilance Branch within the TGA would need to spend a substantial amount of time working on your FOI request to assist in processing and finalising it within the timeframes set by the FOI Act. While undertaking this FOI work, these staff would not be performing their ordinary regulatory functions. This could cause serious delays to and potentially compromise the TGA's role of regulating therapeutic goods under the *Therapeutic Goods Act 1989*. I further note that resources to process your request would also need to be diverted from a range of other areas, and the Legislation, Advice and FOI Branch (being the Branch responsible for processing FOI requests).

20. 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.

21. Following the request consultation process undertaken under section 24AB of the Act, I am satisfied that a practical refusal reasons still exists.

**Additional information regarding decision**

22. The key objectives of the COVID-19 Vaccine Safety Monitoring Plan are:

    (1) Timely collection and management of reports of COVID-19 vaccine adverse events following immunisation
    (2) timely detection and investigation of COVID-19 vaccine safety signals
    (3) timely action to address any COVID-19 vaccine safety concerns
    (4) timely communications to inform the public of emerging COVID-19 vaccine safety; and
    (5) close collaboration and coordination of effort with other vaccine safety stakeholder groups.

23. In order to identify the 30 documents that you have requested in item 2 of your revised scope (above), the TGA would be required to look at each of the 5 key objectives of the COVID-19 Vaccine Safety Monitoring Plan listed above, identify all documents created between February 2021 and February 2025 from the 12 categories listed by you that relate to the individual key objective (noting that these have not been previously identified or related to that objective and would therefore require subjective interpretation of the relationship to that objective) and then select the 6 most recent documents from this list.

24. The TGA would need to repeat the above process 5 times for each of the 5 key objectives.

25. Further, in accordance with item 2 (b) of the your revised scope, if less than 6 documents exist in the categories listed for any objective, the TGA would be required to retrieve any other documents classified or identified as relating to the implementation of that objective, noting again that classification or identification of the relationship of such documents to the key objectives has not previously occurred.

26. Therefore, I assert that not enough information concerning the 30 documents requested has been provided for us to reasonably identify these documents and avoid making subjective decisions on the actual documents falling within scope of this item. As such, a practical refusal reason still exists.

**Exclusion of my name and designation from the notice of decision**

27. Section 26(1)(b) of the FOI Act requires, subject to section 26(2) of the FOI Act, the name and designation of the decision maker to be included in the notice of a decision to refuse to grant access to a document in accordance with the request.

28. Section 26(2) of the FOI Act however does not require the notice of my decision to contain any information that is of such a nature that its inclusion in the document would cause the document to be an exempt document.

29. I have decided not to include my name and designation in the notice of my decision as I consider the inclusion of this information in this notice would cause that part of the notice to become an exempt document as I consider the information is conditionally exempt from release under section 47E(c) of the FOI Act. The reason for my decision is contained below.

***Paragraph 47E(c): certain operations of an agency***

30. A document is conditionally exempt if its disclosure under this Act would, or could reasonably be expected to, do any of the following:

    (a) prejudice the effectiveness of procedures or methods for the conduct of tests, examinations or audits by an agency;

    (b) prejudice the attainment of the objects of particular tests, examinations or audits conducted or to be conducted by an agency;

    (c) have a substantial adverse effect on the management or assessment of personnel by the Commonwealth or by an agency;

    (d) have a substantial adverse effect on the proper and efficient conduct of the operations of an agency.

31. A copy of section 47E is available at **Attachment B**. Relevantly, the effect of paragraph 47E(c) is that a document is conditionally exempt if its disclosure would, or could reasonably be expected to, have a substantial adverse effect on the management or assessment of personnel by the Commonwealth or by an agency.

32. I have decided not to include my name or designation in this correspondence as I consider this information to be exempt under paragraph 47E(c). Release of the information poses a risk of harassment, intimidation or undue pressure on me for the following reasons:

    - It may expose the decision maker to targeted harassment or threats, affecting their ability to perform their duties.
    - Undermine the TGA's management of personnel by discouraging staff from undertaking decision making roles in future.
    - It is widely recognised that significant evolution in the digital environment, including its 'ubiquity, accessibility and longevity', has increased the risk of harassment and targeted criticism for public servants. These risks include the traceability and trackability of personal lives and the risk of physical and online harassment.

- These risks have been compounded by the normalisation of digital communications and publication – contact details may be published to a wider audience, for a longer period of time, and at no cost, on a digital platform.
- The FOI Act does not, of itself, limit those to whom, or the platforms on which, one might choose to publish the documents to which they are given access. Information may be disseminated very broadly and rapidly, and the FOI Act has no mechanism to prevent this dissemination, nor to prevent the information being edited or distorted in any way.
- Media activist trends of 'doxxing' (publishing private information on the internet or identifying information about an individual) have become widespread and mainstream as a method of social retribution for perceived slights against the community in the last few years.

33. I consider that based on recent instances of online harassment from members of the public that have personally targeted TGA staff, in relation to COVID-19 matters, that there is a reasonable expectation that release of my name and designation on this notice could result in an escalation of harassment and threats towards TGA staff.
34. Exposing decision makers in the TGA to threats or harassment when performing their duties, would reasonably be expected to result in the TGA not complying with its obligations under the *Work Health and Safety Act 2011* (WHS Act).
35. Under the WHS Act, the TGA is required to ensure the health and safety of its staff, as far as reasonably practicable. This includes taking steps to eliminate risks to health and safety so far as it is reasonably practicable to do so or minimise the risks if it is not practical to eliminate them. These risks include harassment, intimidation, slander, defamation and online abuse, insults and trolling.
36. As work health and safety relates to the management of personnel, I am satisfied the disclosure of my name and designation relates to the management of personnel.

***Expected affect would both be substantial and adverse to the management of personnel***

37. I must also assess whether the effect mentioned above would be both substantial and adverse to the management of personnel by the TGA.
38. Paragraph 6.18 of the Guidelines provides that the term "substantial adverse effect" broadly means 'an adverse effect which is sufficiently serious or significant to cause concern to a properly concerned reasonable person'.
39. I have decided that the effect of staff being subject to harassment, intimidation or threats in performing their duty would have a substantial and adverse effect on the management of personal by the TGA. This is because the failure of the TGA to comply with its obligations to staff under the WHS Act would negatively affect the TGA's ability to maintain its current staff and to recruit staff in the future. I consider this to be a sufficiently serious concern because of the impact this effect would have on the efficient and effective operation of the TGA.
40. Additionally, I have considered the relevant factors outlined in paragraph 6.111 of the OAIC Guidelines and find that following the COVID-19 pandemic and given the TGA's role in the response, there has been a heightened awareness of the activities that TGA undertakes. The TGA and certain staff members have a more public presence than previously and certain members of the public have directly targeted staff within various areas of the TGA. There have been many previous incidents of staff at the TGA being contacted, harassed and intimidated and I consider that the risk of damage to the wellbeing and safety of decision makers outweighs the considerations for release.

41. Accordingly, I have decided that the release of my name and designation in this notice would have a substantial adverse effect on the management of personnel of the TGA.

42. However, I am required under subsection 11A(5) of the FOI Act to give access to the information unless it would, at this time, on balance, be contrary to the public interest. I do not consider that disclosure of the decision maker's name would advance the objectives of the FOI Act.

43. I consider that the factor in favour of giving access to the information at this time are:

    - general public interest in obtaining access to information held by government; and
    - the importance of transparency in government decision making.

44. I consider that the factors against providing access to the information include:

    - the disclosure of the information could reasonably be expected to expose the decision maker to further targeted harassment or threats; and
    - there is an inherent public interest in maintaining the safety and wellbeing of APS staff.

45. On balance, I am of the view that giving access to the information at this time would be contrary to the public interest.

**Submitting a new request**

46. We acknowledge your attempts to revise the scope of your request to make it processable. In my letter sent to you on 16 May 2025, you were advised that item 1 of your revised scope (submitted on 5 May 2025) was considered to be clear and reasonable to process, and documents relevant to item 1 would likely provide you with information helping you to understand how the TGA implemented its COVID-19 Vaccine Safety Monitoring Plan.

47. The TGA sought your consideration of revising your scope to include item 1 only and that access to these documents may assist you to make a further valid request in the future.

48. Noting the above, we suggest you consider submitting a new request for item 1 of your revised scope (submitted on 5 May 2025) only. You are welcome to submit a new request via the following link: Freedom of information request form | Therapeutic Goods Administration (TGA).

**Review and complaint rights**

49. If you are not satisfied with this decision, you can either seek internal review or apply to the OAIC for review of the decision. Further information can be found on the OAIC website at the following link: www.oaic.gov.au/freedom-of-information/your-freedom-of-information-rights/freedom-of-information-reviews

50. Should you have any enquiries concerning this matter, please contact the FOI Team via email at TGAFOI@health.gov.au or telephone (02) 6289 4630.

Yours sincerely

*Electronically authorised and signed by*

Delegated FOI Decision Maker
Pharmacovigilance Branch
Therapeutic Goods Administration
3 June 2025