Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

[redacted]
Freedom of Information Branch
Office of the Australian Information Commissioner

By email: foidr@oaic.gov.au

OAIC reference: MR22/00538
Agency reference: FOI 3643 | LEX 26100

[redacted]

Response to written notice and direction under ss 55V(2) and 55(2)(e)(ii) of the Freedom of Information Act 1982

1. I refer to your letter dated 9 August 2024 regarding the Information Commissioner review (**IC review**) of a decision by the Australian Government Department of Health and Aged Care (**the Department**) to refuse documents requested by Paul Rekaris (**the applicant**) under the *Freedom of Information Act 1982* (Cth) (**FOI Act**) under cover of which you:

    a. set out your preliminary view in relation to the Department's decision (**OAIC Preliminary View**);

    b. gave a notice requiring the Department to produce a document(s) that records the further searches conducted and submissions relevant to whether the further searches undertaken amounted to 'all reasonable steps', under s 55(2)(e)(ii) of the FOI Act (**the s 55(2)(e)(ii) Notice**); and

    c. gave a notice requiring the Department to conduct further searches for documents and provide evidence of those searches, including the searches checklist, under s 55V(2) of the FOI Act (**the s 55V(2) Notice**).

2. I am instructed to respond on behalf of the Therapeutic Goods Administration, which is a part of the Department, in relation to this matter.

3. Please find below the Department's response to each of the Notices.

The s 55(2)(e)(ii) Notice

Background

4. As you will recall, on 18 February 2022, the applicant made a request for the following information:

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 or 02 6289 4124 Fax: 02 6203 1605
Email: info@tga.gov.au

I request an implementation report on the Covid 19 Vaccine Safety Monitoring Plan as per the key objectives listed in the plan:

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 information and to support public confidence in vaccines

5. close collaboration and coordination of effort with other vaccine safety stakeholder groups

I specifically request a specific report outlining progress of key outputs, outcomes and timelines as per the above objectives.

5. On 27 February 2022, the Department made a decision to refuse access to the document on the basis that it does not exist (s 24A of the FOI Act).

Submissions in response to OAIC Preliminary View

6. We understand from your letter that the OAIC's preliminary view is that it is not satisfied the Department has demonstrated that it has taken all reasonable steps to find the requested document and that the document does not exist on the basis that the Department has adopted an unreasonably narrow approach to the construction of the applicant's request by limiting its searches to a specific document – an evaluation report assessing whether the TGA has achieved the goals and objectives listed in the COVID-19 Vaccine Safety Monitoring Plan (**the Plan**).

7. The Department wishes to clarify that, in making the initial decision, it did not interpret the request as being limited to a single *specific* report, but instead interpreted it as including *any document outlining the progress of implementing the Plan as measured against the objectives set out in the Plan*. The Department considers this to have been reasonable in the circumstances where the applicant has expressly stated '*I specifically request a specific report outlining progress of key outputs, outcomes and timelines as per the above objectives*'. In the context of the request, this indicates that the applicant is seeking a *report* that *outlines the progress* of *key outputs, outcomes and timelines* set out in the Plan and, in doing so, *evaluates* the implementation of the Plan *against its objectives.*

8. However, the Department understands that the OAIC's preliminary view is that *any documents* that *relate to* the implementation of the Plan would be within the scope of the FOI request. The Department considers that a search consistent with the OAIC's preliminary view would involve searching for:

    a. any documents relating to the implementation of any one or more of the five objectives of the Plan set out in the FOI request (**Documents relating to one or more Plan Objectives**); and

    b. any documents relating to the implementation of the Plan in its totality (**Documents relating to the Plan in Total)**.

9. In those circumstances, the Department respectfully makes two submissions.

10. *First*, the Department submits that a search consistent with the OAIC's preliminary view would be so broad as to appear non-responsive to the applicant's request. This is because documents relating to the implementation of the objectives of the Plan would likely include a large number of deliberative and operational documents that would not be a 'specific report outlining progress' and indeed would not be a 'report' at all.

11. *Second,* the Department submits that a search consistent with the OAIC's preliminary view would produce exceedingly voluminous results (as indicated by the below response to the s 55V(2) Notice) such that it appears likely that any decision on those terms would be the subject of a practical refusal on the basis that it would substantially and unreasonably divert the resources of the agency from its other operations.

12. This is because the Plan, which '*builds on the Department of Health's already well-established vaccine safety monitoring activities (known as 'pharmacovigilance') to closely monitor the safety of COVID-19 vaccines…[and] includes details of the TGA's involvement in Australia's broader national vaccine safety surveillance system and how we work closely with states and territories, other government agencies, overseas regulators and expert bodies to ensure a coordinated approach*' [1] is very broad in scope, and we anticipate that a very large number of documents could be said to relate to its implementation.

13. For example, the first objective of the Plan relates to enhanced reporting of adverse events following immunisation (**AEFI**). This objective was described as having five strategic elements. Each strategic element was described as having its own objectives and outputs.[2] Implementing the first strategic element of this first objective of the Plan alone encompassed all associated consumer and health professional communication activities, including Departmental contributions to other government COVID-19 communication products (advertising, articles, and similar materials), to raise awareness of AEFI reporting and educate audiences on how to report. See row 1 of Table 1, and Table 2 in Attachment A for details of searches for documents that would relate to implementation of the first objective of the Plan.

14. We acknowledge that some of the outputs specified in the Plan were objective matters in relation to which a discrete set of documents may exist that could evidence their implementation. For example, the output at item 1.2 '*Updated TGA AEFI reporting forms that capture information specific to COVID-19 vaccines and outline the need for follow-up information on COVID-19 Adverse Events of Special Interest (AESI)*' could be evidenced by updated forms, and the output at item 1.5 '*Criteria for COVID-19 vaccine report escalation and clinical review incorporated into the TGA's standard procedures*' could be evidenced by updates made to documented standard procedures. However, documents that *relate to* the implementation of each of these matters would be significantly higher in number than documents that

[1] Page 1 of the Plan, available at Universal Resource Locator (URL) <https://www.tga.gov.au/sites/default/files/covid-19-vaccine-safety-monitoring-plan.pdf>.

[2] Page 6 of the Plan, available at URL <https://www.tga.gov.au/sites/default/files/covid-19-vaccine-safety-monitoring-plan.pdf>.

evidence their implementation, as documents relating to their implementation would also include deliberative material.

15. Further, some of the outputs specified in the Plan were more subjective in nature, making it difficult to assess whether a particular document would 'relate to' implementation of these outputs. For example, item 1.4 '*The TGA's adverse event report database and team prepared to meet the anticipated increase in data entry and management requirements relating to COVID-19 vaccine AEFI'*, and item 2.2 '*The TGA is prepared to meet the anticipated increase in investigation requirements relating to COVID-19 vaccine AEFI reports'* are outputs relating to the TGA's preparedness to undertake certain activities. While there is unlikely to be a set of discrete documents evidencing the TGA's preparedness (because no audit of preparedness was undertaken), it may be that documents evidencing changes to procedures relating to collection and investigation of AEFIs, or even documents evidencing actual collection and investigation, could be said *to relate* to a preparedness to do so. If the scope was interpreted in this way, then there would likely be a large volume of relevant documents.

Submissions relevant to whether searches amounted to 'all reasonable steps'

16. As you would be aware, the FOI Guidelines provide at s 3.88 – 3.89 (citations omitted) that:

"*The Act is silent on what constitutes 'all reasonable steps'. The meaning of 'reasonable' in the context of s 24A(1)(a) has been construed as not going beyond the limit assigned by reason, not extravagant or excessive, moderate and of such an amount, size or number as is judged to be appropriate or suitable to the circumstances or purpose.*

Agencies and ministers should undertake a reasonable search on a flexible and common sense interpretation of the terms of the request. What constitutes a reasonable search will depend on the circumstances of each request and will be influenced by the normal business practices in the agency's operating environment or the minister's office. At a minimum, an agency or minister should take comprehensive steps to locate documents, having regard to:

- *the subject matter of the documents*
- *the current and past file management systems and the practice of destruction or removal of documents*
- *the record management systems in place*
- *the individuals within an agency or minister's office who may be able to assist with the location of documents, and*
- *the age of the documents*."

17. Having regard to the above, the Department submits that the searches undertaken in support of the initial decision and the subsequent submissions to the OAIC on 28 July 2022 (as referred to at paragraph 7 above) reflect a reasonable search on a flexible and common sense interpretation of the terms of the request. On that basis, the Department submits that it discharged its duty to take 'all reasonable steps' to find the requested document(s) for the purposes of s 24A of the FOI Act in making the initial decision.

18. Notwithstanding this, the Department has now undertaken searches, consistent with the OAIC's preliminary view, for Documents relating to one or more Plan Objectives and Documents relating to the Plan in Total (as characterised at 8 above). For completeness, the Department respectfully submits that those searches go beyond 'all reasonable steps' insofar as they reflect a search that does not align with a common sense interpretation of the terms of the request.

The s 55V(2) Notice

19. As referred to above, the Department has conducted further searches and provides the following for consideration by the OAIC:

    a. Two tables at **Attachment A**, which deal with searches for Documents relating to one or more Plan Objectives:

        i. Table 1 sets out the approximate number of documents, pages and third parties identified by a non-exhaustive (sampling) search for documents relevant to the scope of the applicant's request as characterised by the OAIC's preliminary view *when assessed against each objective of the Plan*. This search is characterised as non-exhaustive (sampling) due to the complexities outlined in paragraphs 6 - 18 above.

        ii. Table 2 sets out a sample of relevant documents identified in relation to item 1 of Table 1. This search was conducted on five 'containers' within TRIM and Promap using search terms that focussed on 'policy and procedure documents related to the implementation of the COVID-19 vaccine pharmacovigilance plan'. This table therefore reflects a small subset of documents identified in relation to the one of the five items of the FOI request, as characterised in Table 1.

    b. Two tables at **Attachment B**, which deal with Documents relating to the Plan in Total:

        i. Table 3 sets out the approximate number of documents, pages and third parties identified by a search, by a Senior Medical Officer within the Pharmacovigilance Branch, for documents relevant to the scope of the applicant's request as characterised by the OAIC's preliminary view *when assessed in its totality*, e.g. '*Any documents that relate to the implementation of the 'Covid 19 Vaccine Safety Monitoring Plan'.*

        ii. Table 4 sets out the same search, undertaken by an Assistant Director in the Vaccines Surveillance Section of the Pharmacovigilance Branch, expanded to encompass the term 'pharmacovigilance'.

    c. **Attachment C**, being the searches checklist provided by the OAIC; and

    d. **Attachment D**, being further documents recording the searches conducted, including internal notes by persons undertaking the searches.

20. Given the OAIC's preliminary view and the Department's above submissions, the Department respectfully requests that it be given an opportunity to clarify any

matters relating to how the searches have been undertaken should the OAIC remain of the view that the Department has not taken all reasonable steps in this matter.

21. Please do not hesitate to contact [redacted] or at [redacted] should you wish to discuss this matter.

Yours sincerely

20/09/2024

[redacted]

Principal Lawyer
Regulatory Legal Services Branch

20 September 2024

Attachment A

Sample search for documents relevant to the scope of the applicant's request as characterised by the OAIC in its preliminary view

This table sets out the approximate number of documents, pages and third parties identified by a non-exhaustive (sampling) search for documents relevant to the scope of the applicant's request as characterised by the OAIC's preliminary view when assessed against each objective in the Plan. This search is characterised as non-exhaustive (sampling) due to the complexities outlined at paragraph 6 - 18 above.

TABLE 1				
Item	**Any documents that relate to...**	**OAIC interpretation**	**TGA interpretation for purpose of sample search**	**Databases searched/staff consulted**
1	timely collection and management of reports of COVID-19 vaccine adverse events following immunisation	Any documents that relate to the implementation of the timely collection and management of reports of COVID-19 vaccine adverse events following immunisation	Policy and procedure documents that relate to the implementation of timely collection and management of reports of COVID-19 vaccine adverse events following immunisation, focused on or around February 2022, largely excludes non-vaccine specific documents. Please note: This time point reflects the height of vaccine adverse event activity and as a result new processes were being created and tested at a rapid pace across a large number of teams. These documents are held in multiple systems and it is not possible	TRIM Promap Note – sample of 4 containers only >303 pages in addition to >36 promap[3] processes Within this sample search, initial audit records identified between 23-138 pages of versions that may be active at February 2022 but require pulling audit records to confirm. Schedule outlined later in this document. **Consulted:** Director of Adverse Event and Medicines Defect Section, Assistant Secretary of Pharmacovigilance Branch, TGA FOI team.

[3] Please note that Promap software is used to establish interaction work flow processes. For example, one 'Promap Process' might set out how to respond to an external query in a particular context. The Promap Process in that example might set out a flow chart which is approximately one page in size. However, each step in that process can be 'selected' and expanded, effectively creating multiple 'new pages'. It is therefore very difficult (or not possible) to accurately quantify the number of pages in each 'Promap process'. In saying that, we think it would be reasonable to estimate that the median 'Promap process' would be 5 pages.

TABLE 1				
Item	**Any documents that relate to...**	**OAIC interpretation**	**TGA interpretation for purpose of sample search**	**Databases searched/staff consulted**
			to search by documents in existence at a specific date. To accurately identify documents falling within this part of the scope, each individual policy or procedure document would need to be individually audited for any versions or amendments that were in existence at the time.	
2	timely detection and investigation of COVID-19 vaccine safety signals	Any documents that relate to the implementation of the timely detection and investigation of COVID-19 vaccine safety signals	Documents that detail the protocol and/or methodology that was intended to be used to quantitatively and/or statistically identify potential safety signals related to the COVID-19 vaccines in the TGA's Adverse Event Management System and therefore the implementation of timely detection and investigation of COVID-19 vaccine safety signals (note, excludes all other types of procedures and protocols, SOPs, investigation documents, signal analysis, data interpretation, non-vaccine specific documents. etc).	TRIM Sample of documents from 3 teams, schedule published in FOI 4940, majority of documents released in FOI 5082 >679 pages (calculated via FOI 4940 schedule of documents) **Consulted:** Assistant Secretary of Pharmacovigilance Branch, TGA FOI team. Note - audit records not pulled, would be extensive time involved to achieve this sample with audit records.

TABLE 1				
Item	**Any documents that relate to...**	**OAIC interpretation**	**TGA interpretation for purpose of sample search**	**Databases searched/staff consulted**
3	timely action to address any COVID-19 vaccine safety concerns	Any documents that relate to the implementation of the timely action to address any COVID-19 vaccine safety concerns	For 1 team at the TGA only and for safety concerns identified by the TGA only (excluding safety concerns identified by pharmaceutical companies), all documents related to the timely action to address the TGA identified safety concern (excludes all documents and committee meetings *investigating* TGA identified safety concerns, searching for regulatory actions initiated by 1 team only, excludes non-vaccine specific documents).	TRIM (1 team's regulatory actions noting >4 teams across 3 branches may have undertaken regulatory action) >406 pages (58 TGA-initiated regulatory actions across the COVID-19 vaccine class, 50 Product Information updates, multiply by 7 pages per action minimum, excludes all other types of regulatory actions and actions to address safety concerns. **Consulted:** Director of Regulatory Outcomes Team, Assistant Secretary of Pharmacovigilance Branch, TGA FOI team. Note - audit records not pulled, would be extensive time involved to achieve this sample with audit records.
4	timely communications to inform the public of emerging COVID-19 vaccine safety information and to support public confidence in vaccines	Any documents that relate to the implementation of the timely communications to inform the public of emerging COVID-19 vaccine safety information and to support public	For 1 team at the TGA only and for safety concerns identified by the TGA only (excluding safety concerns identified by pharmaceutical companies), all documents related to the timely communications to inform the public of emerging COVID-19 vaccine safety information and to support public confidence in vaccines (communication initiated by 1 team	TRIM (1 teams public communications to allow sample search) >250 pages (Total of approximately 50 COVID-19 vaccine safety reports, each approx. 3 pages but report pages excluded due to publication, with approx. 5

TABLE 1				
Item	**Any documents that relate to...**	**OAIC interpretation**	**TGA interpretation for purpose of sample search**	**Databases searched/staff consulted**
		confidence in vaccines	only, excludes Department of Health public communications, excludes ACV committee meetings, ATAGI and any publications from the laboratory branch for batch release etc excludes non-vaccine specific documents).	internal documents per publication of the COVID-19 vaccine safety report (under-estimation). **Consulted:** Assistant Secretary of Pharmacovigilance Branch, TGA FOI team.
5	close collaboration and coordination of effort with other vaccine safety stakeholder groups	Any documents that relate to the implementation of close collaboration and coordination of effort with other vaccine safety stakeholder groups	Unable to meaningfully interpret into a searchable item. This would include all communications with the ACV, ACM, Department of Health, ATAGI, AusVaxSafety, NCIRS, every state and territory government, each COVID-19 vaccine pharmaceutical company, each international regulatory body including all ICMRA and ACCESS meetings, all state and territory Coroner's.	Unable to perform a relevant sample search. Also involves >4 branches of TGA and >40 third parties. Example: for one ICMRA sub-group meeting alone, >274 documents of varying page numbers and 30 third parties (ICMRA medicines regulatory authorities from every region in the world, with the World Health Organisation (WHO) as an observer). (Used COVID-19 Pharmacovigilance network meeting documents in container E20-111542. This represents one sub-group of ICMRA, with multiple other ICMRA groups in operation at the time). **Consulted:** Assistant Secretary of Pharmacovigilance Branch Note - audit records not pulled, would be extensive time involved to achieve this sample with audit records.

Sample Of Relevant Documents identified in relation to item 1 of Attachment A

This table sets out a sample of relevant documents identified in relation to item 1 of Table 1, being a non-exhaustive (sampling) search for documents relevant to the scope of the applicant's request as characterised by the OAIC's preliminary view. This search was conducted on five 'containers' within TRIM and Promap using search terms that focussed on 'policy and procedure documents related to the implementation of the COVID-19 vaccine pharmacovigilance plan'. While records identified were in existence at the time of the FOI request, please note that most have been subject to subsequent amendments since that time. As such, further search and retrieval would be required to utilise the 'historical record' function in TRIM to locate the version of the document as was in existence at the time of the FOI request.

This table therefore reflects a small subset of documents identified in relation to the one of the five items of the FOI request, as characterised in Table 1.

TABLE 2							
Section of FOI request	**TRIM container**	**Current number of documents[4]**	**Number of documents definitively in existence at time of request[5]**	**Pages**	**Location**	**Description**	**Third parties**
1	E18-211453	25	12	1-6 per document	TRIM	AEMDS SOPs	TBC - State and territory governments, vaccine pharmaceutical companies

[4] This is the number of documents currently in the file.

[5] This is the number of documents that have been identified as definitively being in existence at the time of the FOI request using the 'Date Created' function in TRIM. However, the 'Date Created' function indicates when a document was saved to TRIM, not the date on which a document was first drafted. This means that documents drafted and stored on desktop devices or exchanged via email and saved to TRIM at a later date will appear to have been 'created' at that later date. Accordingly, and noting the pace of administrative change during the COVID-19 pandemic, the Department anticipates that the 'Date Created' function cannot be relied upon to identify documents that were in existence at the time of this FOI request. Rather, each record in the file will need to be reviewed individually to ascertain whether it was in existence (in some form) at the time of the FOI request. The Department has therefore included the total number of documents presently in each file for completeness.

TABLE 2							
Section of FOI request	**TRIM container**	**Current number of documents[4]**	**Number of documents definitively in existence at time of request[5]**	**Pages**	**Location**	**Description**	**Third parties**
1	E21-244147	16	0	1-6 per document	TRIM	Templates and coding processes	TBC - State and territory governments, vaccine pharmaceutical companies
1	E21-244150	23	5	1-6 per document	TRIM	Case processing instructions	TBC - State and territory governments, vaccine pharmaceutical companies
1	E21-0244155	6	1	1-6 per document	TRIM	Now superseded case escalation and JIC report templates	TBC - State and territory governments, vaccine pharmaceutical companies
1	E21-253281	31	5	1-6 per document	TRIM	Coding and process updates	TBC - State and territory governments, vaccine pharmaceutical companies
1	https://au.promapp.com/dohhprg/Process/Mi	N/A		5[6]	Promap	Enquires	

[6] As noted above at footnote 3, Promap software is used to establish interaction work flow processes. For example, one 'Promap Process' might set out how to respond to an external query in a particular context. The Promap Process in that example might set out a flow chart which is approximately one page in size. However, each step in that process can be 'selected' and expanded, effectively creating multiple 'new pages'. It is therefore very difficult (or not possible) to accurately quantify the number of pages in each 'Promap process'. In saying that, we think it would be reasonable to estimate that the median 'Promap process' would be 5 pages. On that basis, we have included 5 pages as an estimate in relation to each of the Promap processes identified in this sample search.

TABLE 2							
Section of FOI request	**TRIM container**	**Current number of documents[4]**	**Number of documents definitively in existence at time of request[5]**	**Pages**	**Location**	**Description**	**Third parties**
	nimode/Permalink/HkTfxJp4iGM5gvEaxATtdg						
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/E4wwgFsR5619FX7Ew3cmHX	N/A		5	Promap	Enter case administration	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/FikWbonUGiY7sS5RVtVlGM	N/A		5	Promap	Enter CIOMS into AEMS	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/CUG00mPfNdZ9DwapJM1GM9	N/A		5	Promap	Enter data from report into AEMS system	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/DM75vyjapNk4nejwZBhPJX	N/A		5	Promap	Enter reaction details (coding)	

TABLE 2							
Section of FOI request	**TRIM container**	**Current number of documents[4]**	**Number of documents definitively in existence at time of request[5]**	**Pages**	**Location**	**Description**	**Third parties**
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/FR50KvUotnkRsvGLRc4BGQ	N/A		5	Promap	Enter reporter details	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/Fjbp2uwVS3EYEg30GgHpX6	N/A		5	Promap	Entering a literature review into AEMS	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/E24VMGTch3y63WQyzumKKf	N/A		5	Promap	Entering vaccine report into CRM	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/HK7j8ct2Fepc0cauu2nIRn	N/A		5	Promap	Escalate a coded report in AEMS	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/Dz3Qkunq1sfY4aYIME6jr2	N/A		5	Promap	Escalation of adverse event following immunisation	

TABLE 2							
Section of FOI request	**TRIM container**	**Current number of documents[4]**	**Number of documents definitively in existence at time of request[5]**	**Pages**	**Location**	**Description**	**Third parties**
						(AEFI) from AEMDS to SIU	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/Drdu0Xp4afffFGDIOXG5Eq	N/A		5	Promap	Liaise with PVIP	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/BX0AnL5TmOcxJ4CIDXm75G	N/A		5	Promap	Process a fatal AEFI report	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/F7D1G2GN8aK9iNVshrWytS	N/A		5	Promap	Receive ADR, file and management ADR in box	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/BfHomDznwWgaZGDTE66OXw	N/A		5	Promap	Receive and enter ADR	

TABLE 2							
Section of FOI request	**TRIM container**	**Current number of documents[4]**	**Number of documents definitively in existence at time of request[5]**	**Pages**	**Location**	**Description**	**Third parties**
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/Fd4lsu1ASlgU0SpDnv25DB	N/A		5	Promap	Receive report via email, online report of upload	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/Ef8mzB3nYgvDpRsUicGVfC	N/A		5	Promap	Receive report via fax or mail	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/HMlY24ExtJr55QNDxVNwvO	N/A		5	Promap	Review a coded report if AEMS	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/CByX4Xe5UuuyoKHi81lO1f	N/A		5	Promap	Review of ADR cases	
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/ETJZ8gVfzGFxsdSsuf8hmu	N/A		5	Promap	Select and prepare to enter an adverse drug reaction report into AEMS	

TABLE 2							
Section of FOI request	**TRIM container**	**Current number of documents[4]**	**Number of documents definitively in existence at time of request[5]**	**Pages**	**Location**	**Description**	**Third parties**
1	https://au.promapp.com/dohhprg/Process/Minimode/Permalink/BM7vbcqdLQwnuzLM9Ljlle	N/A		5	Promap	Vaccine safety surveillance system - escalate case	

Attachment B

Sample searches undertaken by Senior Medical Officer within the Pharmacovigilance Branch of the Medicines Regulation Division on 21/08/2024

This table sets out the approximate number of documents, pages and third parties identified by a search for documents relevant to the scope of the applicant's request as characterised by the OAIC's preliminary view when assessed in its totality, e.g. '*Any documents that relate to the implementation of the 'Covid 19 Vaccine Safety Monitoring Plan'.*

TABLE 3					
No	**Search Terms, words and phrases**	**Database Searched**	**Number of Results**	**Comments**	**Relevant Documents found in scope**
1	'Implementation of COVID-19 Vaccine Safety Monitoring Plan'	TRIM	3 documents	D22-5123866 – consumer email request for update on implementation of the COVID-19 vaccine safety monitoring plan D22-5186056– TGA response to consumer email request for update on implementation of the COVID-19 vaccine safety monitoring plan D22-5168137– TGA response to consumer email request for update on implementation of the COVID-19 vaccine safety monitoring plan	0
2	'Implementation vaccine monitoring plan'	TRIM	13 documents	Above results plus 10 FOI emails related to FOI 3643 and FOI 3623	0
3	'Audit report COVID-19 vaccine safety monitoring'	TRIM	0	Nil	0
4	'Audit COVID-19 vaccine'	TRIM	>531 **containers** of documents	Relate to manufacturing audits, vaccine taskforce (non-TGA), COVID-19 vaccine program (non-TGA), COVID-19	0

TABLE 3					
No	**Search Terms, words and phrases**	**Database Searched**	**Number of Results**	**Comments**	**Relevant Documents found in scope**
				vaccine roll-out (non-TGA), COVID-19 vaccine treatments manufacturing audits	
5	'COVID 19 Vaccine Safety Monitoring Plan'	TRIM	20 documents	Results for search 1 + 2, plus internal communication leading to publication of the COVID-19 vaccine safety monitoring plan, email sharing of plan with ATAGI.	0
6	'Implementation vaccine safety'	TRIM	86 records including **containers** of documents	Results from item 5, TGA containers from 2001-2008 (prior to COVID-19 vaccines), results from non-TGA areas including health promotion and safety regarding the implementation of the COVID-19 vaccine campaign, results from HPV vaccine implementation.	0

Sample searches undertaken by Assistant Director in the Vaccines Surveillance Section of the Pharmacovigilance Branch on 22/08/2024

This table sets out the approximate number of documents, pages and third parties identified by a search, by an Assistant Director within the Vaccines Surveillance Section of the Pharmacovigilance Branch, for documents relevant to the scope of the applicant's request as characterised by the OAIC's preliminary view *when assessed in its totality*, e.g. '*Any documents that relate to the implementation of the 'Covid 19 Vaccine Safety Monitoring Plan. This table therefore reflects the same searches undertaken in Table 3 (with the exception of expanding at item 7 and 8 to encompass the term 'pharmacovigilance') but undertaken by a different staff member for quality assurance'.*

TABLE 4					
Search No	**Search Terms, words and phrases**	**Database Searched**	**Number of Results**	**Comments**	**Relevant Documents in scope**
1	'Implementation of COVID-19 Vaccine Safety Monitoring Plan'	TRIM	12	Four documents are email responses to Mr Paul Rekaris who wrote to the TGA to request an update on the implementation of the *COVID-19 vaccine safety monitoring plan*. Eight documents are about the initial FOI request from Mr Paul Rekaris. Mr Rekaris already has this information.	0
2	'Implementation vaccine monitoring plan'	TRIM	13	12 documents as described in line one. One paper file from 2008. Mr Rekaris already has the information in the 12 emails. The document from 2008 is not relevant to the scope of the request.	0
3	'Audit report COVID-19 vaccine safety monitoring'	TRIM	NIL		
4	'Audit COVID-19 vaccine'	TRIM	531	Scanned through titles of documents and containers. They appear to be related to an audit of the manufacture and rollout of the COVID-19 vaccines. NIL records identified as related to the scope of the request.	0

TABLE 4					
Search No	**Search Terms, words and phrases**	**Database Searched**	**Number of Results**	**Comments**	**Relevant Documents in scope**
5	'COVID 19 Vaccine Safety Monitoring Plan'	TRIM	20	Seven documents about the *COVID-19 vaccine safety monitoring plan* and the remaining 13 emails responding to Mr Rekaris email and FOI request.	0
6	'Implementation vaccine safety'	TRIM	NIL		
7	Implementation COVID-19 vaccine pharmacovigilance plan	TRIM	1	DRAFT Pharmacovigilance Branch input about the COVID-19 vaccine pharmacovigilance plan for inclusion in the Australian COVID-19 vaccination Policy. The final policy document is publicly available at: https://www.health.gov.au/sites/default/files/documents/2020/12/covid-19-vaccination-australian-covid-19-vaccination-policy.pdf The Pharmacovigilance Branch input is a summary of the COVID-19 vaccine pharmacovigilance plan and is not relevant to the scope of the request.	0
8	Audit report COVID-19 vaccine pharmacovigilance plan	TRIM	NIL		

At

Attachment C – Search Checklist

Search location	Has search been undertaken?	If search has not been undertaken, provide reasons why not.	If search has been undertaken, provide details of who did the search, when, the parameters of the search and the outcome of the search.
Internal record management system [insert name]	Yes - TRIM Promapp		See attached
Digital files in group drives and Home drives	Yes - TRIM Promapp		See attached
Any stand-alone computers, laptops or tablets	No	Sample search only, also unlikely to contain team process documents	See attached
Mobile phones (text messages and instant messaging applications)	No	Sample search only, also unlikely to contain team process documents	See attached
Hand written notes in diaries or notebooks	No	Sample search only, also unlikely to contain team process documents	See attached
Records in Microsoft Outlook Calendars and digital diaries	No	Sample search only, also unlikely to contain team process documents	See attached
Hardcopy files	No	TGA is 'paperless' with documents stored in TRIM in February 2022. Paper files dated earlier and not relevant to request	See attached
Email accounts	No	Sample search only, also unlikely to contain team process documents	See attached

All documents currently with an external provider (solicitors, consultants etc)	No	Not relevant to sample search	See attached
Any other locations **Accc**	No	Not relevant to sample search	See attached

Attachment D

FOI 3643
Request for Further Search and Retrieval
(Internal notes and calculations)

Conducted By: Principal Medical Officer, Therapeutic Goods Administration
Date: 21/08/2024

Initial Request:

"I request an implementation report on the Covid 19 Vaccine Safety Monitoring Plan as per the key objectives listed in the plan:

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 information and to support public confidence in vaccines
5. close collaboration and coordination of effort with other vaccine safety stakeholder groups

I specifically request a specific report outlining progress of key outputs, outcomes and timelines as per the above objectives."

OAIC interpretation:

'Any documents that relate to the implementation of the 'Covid 19 Vaccine Safety Monitoring Plan'

Challenges to interpretation:

- The scope requests all documents produced by >5 separate teams, multiple branches and refers to multiple IT and document management systems.
- If a search was possible using varied interpretations of scope, no guarantee that all relevant documents have been identified.
- If a search was possible using varied interpretations of scope, a review all documents, procedures, templates, analysis plans, discussions and outcomes is not likely to answer the applicant's question of '*I specifically request a specific report outlining progress of key outputs, outcomes and timelines as per the above objectives'.*

Sample Search Result:

- Sample searching revealed **more than 2,218 relevant pages** using a very limited sample scope for items 1-5. All interpretations and calculations are set out below with references and rationale. Please note that a significant amount of documents in scope of this request are already in the public domain. These are also identified below.

From: [redacted], s 22 <[redacted]@health.gov.au>
Sent: Thursday, August 22, 2024 2:36 PM
To: [redacted] <[redacted]@health.gov.au>
Cc: [redacted] <[redacted]@health.gov.au>; [redacted] <[redacted]@health.gov.au>; [redacted] <[redacted]@health.gov.au>; [redacted] <[redacted]@health.gov.au>
Subject: FW: Request for assistance with FOI sample search exercise - MR22/00538 , LEX 26100 [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Hi [redacted],

As requested, please see below for an updated search for *'any documents that relate to … the implementation of the COVID 19 Vaccine Safety Monitoring Plan [in its totality]',* kindly completed by [redacted] within VSS.

Happy to discuss if there are any queries with the additional searches performed.

[redacted]

[redacted] BSc MBBS MPH *(she/her)*

A/g Director, Vaccines Surveillance Section

Pharmacovigilance Branch

Medicines Regulation Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: 07 3360 2573 | E: [redacted]@health.gov.au

This email comes to you from Turrbal and Yuggera country

Location: 160 Ann St, Brisbane. Queensland. 4000

PO Box 9848, Canberra ACT 2601, Australia

Office hours: MON (9-2) | Tue (9-2) | WED | THUR | FRI

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: [redacted], [redacted] <[redacted].[redacted]@health.gov.au>
Sent: Thursday, August 22, 2024 2:23 PM
To: [redacted], [redacted] <[redacted].[redacted]@health.gov.au>
Subject: RE: Request for assistance with FOI sample search exercise - MR22/00538 , LEX 26100 [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Hi [redacted]

I have conducted a search in TRIM for any documents related to the implementation of the *COVID-19 vaccine safety monitoring plan.* I added two rows to the table provided by [redacted] (rows 7 and 8) to include pharmacovigilance in the search. The results are below and as you can see I

Search No	Search Terms, words and phrases	Database Searched	Number of Results (using 'count' function in TRIM)	Comments	Relevant Documents in scope
1	'Implementation of Covid-19 Vaccine Safety Monitoring Plan'	TRIM	12	Four documents are emails responses to Mr Paul Rekaris who wrote to the TGA to request update on the implementation of the *COVID-19 vaccine safety monitoring plan* Eight documents are about the initial FOI request from Mr Paul Rekaris.	NIL. Mr Rekaris already has this information.
2	'Implementation vaccine monitoring plan'	TRIM	13	12 documents as described in Line one. One paper file from 2008.	NIL. Mr Rekaris already has the information in the 12 emails. The document from 2008 not relevant either.
3	'Audit report COVID-19 vaccine safety monitoring'	TRIM	NIL		
4	'Audit COVID-19 vaccine'	TRIM	531 records	Scanned through titles of documents and containers. They appear to be related to an audit of the manufacture and rollout of the COVID-19 vaccines.	NIL records identified as related to the *COVID-19 vaccine safety monitoring plan*
5	'Covid 19 Vaccine Safety Monitoring Plan'	TRIM	20	Seven documents about the *COVID-19 vaccine safety monitoring plan* and the remaining 13 emails responding to Mr Rekaris email and FOI request.	NIL.
6	'Implementation vaccine safety'	TRIM	NIL		
7	Implementation COVID-19 vaccine pharmacovigilance plan	TRIM	1 document	DRAFT PB input about the COVID-19 vaccine pharmacovigilance plan for inclusion in the Australian COVID-19 vaccination Policy. The final Policy document is publicly available at: https://www.health.gov.au/sites/default/files/documents/2020/12/covid-19-vaccination-australian-covid-19-vaccination-policy.pdf	Not in scope.

				The PB input is a summary of the COVID-19 vaccine pharmacovigilance plan and does not include any timelines for each planned action.	
8	Audit report COVID-19 vaccine pharmacovigilance plan	TRIM	NIL		

have been unable to find any relevant documents in this search. If you have any other suggestions for search terms, I will conduct further searches as necessary.

Regards

[redacted] (she/her)

Vaccine Surveillance Section

Medicines Regulation Division | Health Products Regulation Group | Pharmacovigilance Branch

Australian Government Department of Health and Aged Care

E: [redacted]@health.gov.au

Location: Therapeutic Goods Administration

PO Box 100, Woden ACT 2606, Australia

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Important: *This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission.*

From: [redacted], [redacted] <[redacted].[redacted]@health.gov.au>
Sent: Wednesday, August 21, 2024 5:12 PM
To: [redacted], [redacted] <[redacted].[redacted]@health.gov.au>
Subject: FW: Request for assistance with FOI sample search exercise - MR22/00538 , LEX 26100 [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

From: [redacted], [redacted] <[redacted].[redacted]@health.gov.au>
Sent: Wednesday, August 21, 2024 5:08 PM
To: [redacted], [redacted] <[redacted].[redacted]@health.gov.au>
Cc: [redacted], [redacted] <[redacted].[redacted]@health.gov.au>; [redacted], [redacted] <[redacted].[redacted]@health.gov.au>; [redacted], [redacted] <[redacted].[redacted]@health.gov.au>
Subject: Request for assistance with FOI sample search exercise - MR22/00538 , LEX 26100 [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Dear [redacted],

I hope that you have been keeping well. I was wondering if you or a member of your team might be able to assist PB and RLSD with an FOI sample search exercise.

Background: Back in 2022, PB refused a request for FOI 3643 based on a 'no documents' finding. This is currently with the OAIC who have asked that we undertake a further search and retrieval process. After discussions with [redacted] and RLSD, I have already undertaken a range of sample searches to address the OAIC request. The associated documents and email chain have all of the context if you need it, but the request of you is (hopefully) more straight forward….

Request of you or a team member: To demonstrate that we have undertaken all reasonable steps to identify relevant documents, it would be appreciated if a second team member could also undertake searches. RLSD describe the sample search required as: *'any documents that relate to … the implementation of the COVID 19 Vaccine Safety Monitoring Plan [in its totality]'.* For sample search purposes this may involve searching for "COVID 19 Vaccine Safety Monitoring Plan" and undertaking a random sampling exercise to identify any documents that deal with the implementation of the Plan in its totality – though you are very welcome to adopt any alternative approach that might address this in your view. Please note that I have also undertaken various sample searches relating to each objective of the safety monitoring plan and we do not require you to repeat these.

For the repeated searches, you are welcome to use the terms that I chose and fill in this table below. Please feel free to add any new terms/phrases as new line items.

Sample searches undertaken by XXX on XXX

Scope: '*any documents that relate to … the implementation of the COVID 19 Vaccine Safety Monitoring Plan [in its totality]'*

Search No	Search Terms, words and phrases	Database Searched	Number of Results (using 'count' function in TRIM)	Comments	Relevant Documents in scope

1	'Implementation of Covid-19 Vaccine Safety Monitoring Plan'	TRIM			
2	'Implementation vaccine monitoring plan'	TRIM			
3	'Audit report COVID-19 vaccine safety monitoring'	TRIM			
4	'Audit COVID-19 vaccine'	TRIM			
5	'Covid 19 Vaccine Safety Monitoring Plan'	TRIM			
6	'Implementation vaccine safety'	TRIM			

I expect this will take no longer than 30mintues. If you are able to fill in the above table, please return it via email to [redacted]@health.gov.au. If possible, a response by next **Wednesday 28 August** would be appreciated.

I am away for the next two days (back next Monday). If the timeline is not workable or you have questions, I am sure that [redacted], [redacted] and [redacted] will be able to assist in the meantime.

Thank you very much for considering this request.

Kind Regards,

[redacted]

Principal Medical Advisor, MRD Decision Review

Medicines Regulation Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: 02 6289 7252 | E: [redacted]@health.gov.au

PO Box 100, Woden ACT 2606, Australia

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