Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D22-5201218

Mr [redacted]
Email: [redacted]

Dear [redacted]

FREEDOM OF INFORMATION REQUEST FOI 3643
Notice of Decision

1. I refer to your request dated 18 February 2022 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following document:

> *"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."*

Decision Maker

2. I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

3. I have interpreted your request as being for an evaluation report assessing whether the TGA has achieved the goals and objectives listed in the COVID-19 Vaccine Safety Monitoring Plan.
4. Unfortunately, I am unable to continue to process your request because the document you have requested does not exist. Therefore, I am notifying you of my decision to refuse your request for access under section 24A of the FOI Act.

Reasons for Decision

5. Despite a thorough and complete search, the document you have requested does not exist. In these circumstance, section 24A of the FOI Act states that an agency is able to refuse (discontinue processing) the request. Specifically, the FOI Act states:

   requests may be refused if all reasonable steps have been taken to find a document and the document does not exist.

6. Please be assured that the TGA's electronic databases, files and corporate file lists have been searched and following these searches, I am satisfied that all reasonable steps have been taken to find the document requested. However, the document you have requested does not exist.

7. The reasons the document you have requested does not exist is because the TGA does not hold an 'implementation report' on the COVID-19 vaccine safety monitoring plan.

8. While the TGA continues to monitor the progress of the five objectives listed in your request and has ample documentation demonstrating compliance in those objectives, the TGA does not have a single, specific evaluation report outlining progress.

Direction to Publicly Available Information

Objectives 1– 4 of the COVID-19 Vaccine Safety Monitoring Plan

9. Objectives 1-4 of the COVID-19 vaccine safety monitoring plan (as outlined above in the scope of your request) are captured by the Database of Adverse Events Notification (**DAEN**) and the COVID-19 vaccine weekly safety reports.

10. By way of background, all adverse event reports submitted to the TGA are evaluated, duplicate reports are rejected, and the information contained therein is uploaded to the Database of Adverse Event Notifications – medicines (DAEN). The DAEN contains information on all adverse events reported to the TGA following administration of a medicine, including the COVID-19 vaccines.

11. As of 19 August 2021, the TGA has reduced the time between adverse event reports being accepted into our database and published on the DAEN from 90 days to 14 days to address the strong public interest in adverse event reports relating to COVID-19 vaccinations and allows reports for vaccines to be made publicly available more quickly (pursuant to Item 4).

12. Adverse event reporting data provides a source from which to detect patterns of events that indicate a possible safety issue, or 'safety signals'. The TGA conducts regular statistical analyses of adverse event data to detect signals, in addition to closely monitoring the occurrence of 'adverse events of special interest'. Investigation of safety signals may involve activities such as more detailed analysis and review of adverse event report data, consideration of published literature or information from medicines regulators in other countries, and review of safety data from international use of the vaccine provided by the vaccine sponsor.

13. The TGA publishes a COVID-19 vaccine weekly safety report, which can be accessed at: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report. The report includes summaries of the latest safety information regarding COVID-19 vaccines, including the outcomes of significant safety investigations, and information about regulatory actions taken as a result of TGA's safety monitoring.

Objective 5 of the COVID-19 Vaccine Safety Monitoring Plan

14. The TGA has worked closely with states and territories, other government agencies, overseas regulators, and expert bodies to ensure a coordinated approach to COVID-19 vaccine safety.

15. Examples of this collaboration include:

    a. co-chairing, with the UK Medicine and Healthcare products Regulatory Agency, regular meetings of international medicines regulators to share information about COVID-19 vaccine safety

    b. holding regular meetings with state and territory jurisdictional immunisation coordinators to discuss emerging safety information and communications

    c. providing regular briefings to ATAGI COVID-19 working groups to inform aspects of the vaccine roll-out

    d. working with the National Centre for Immunisation Research and Surveillance to share information and characterise significant vaccine safety issues

    e. seeking expert advice from the Advisory Committee for Vaccines on COVID-19 vaccine monitoring activities and safety issues.

Review and Complaint Rights

16. 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/reviews-and-complaints/

17. If you have any queries regarding this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

[redacted]
gilance Branch
Therapeutic Goods Administration
27 February 2022