Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-3469684

Long Standing Member of a Religious Community in Western Australia
Email: foi+request-8178-c553524a@righttoknow.org.au

Dear Applicant

FREEDOM OF INFORMATION REQUEST FOI 3500
Notice of Decision

1. I refer to your request dated 11 December 2021 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:

   '- Deaths in Australia after 3 days from COVID 19 Vaccine

   - Deaths in Australia after 3 weeks from a COVID 19 Vaccine

   - Deaths in Australia after 3 months from a COVID 19 Vaccine.

   I am not talking about volunterry reporting system, I am not talking about what TGA considers an adverse event, I am asking about the death rate, causal or not, of these groups'.

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. The TGA is unable to process your request because the documents you are seeking do 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

4. Section 24A of the FOI Act states that an agency may refuse (discontinue processing) a request where documents do not exist. 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.'

5. By way of background, the TGA does not collect data on *all* deaths in Australia which occur after administration of a COVID-19 vaccine. Rather, the TGA relies on voluntary reporting of adverse event from patients, members of the public, health practitioners and/or hospitals and state or territory health departments. Companies supplying vaccines are legally required to report serious adverse events to the TGA. The information given to the TGA by the aforementioned parties is then published on the Database of Adverse Events (**DAEN**).

6. The data you are requesting would require linkage of data sets that are not held by the TGA. As your request excludes voluntary reporting, there are therefore no documents which are held by the TGA that fall within the scope of your request.

Publicly Available Information

7. Adverse events reported to the TGA can be found in the DAEN. This can be accessed via the following link: https://www.tga.gov.au/database-adverse-event-notifications-daen.

8. In addition, the TGA publishes a weekly COVID-19 vaccine safety report, which can be accessed via the following link: http://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report. Both the DAEN and weekly safety report contain information falling within the scope of your request involving the number of deaths in Australia reported after vaccination against COVID-19.

Review and Complaint Rights

9. 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/

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

Yours sincerely

Signed electronically

Dr Claire Larter
Director
Pharmacovigilance Branch
Therapeutic Goods Administration
06 January 2022