



**Australian Government**

**Department of Health and Aged Care**

Therapeutic Goods Administration

Ms Deborah-May Torrens

**Email:** [foi+request-11702-a6079a80@righttoknow.org.au](mailto:foi+request-11702-a6079a80@righttoknow.org.au)

Dear Ms Torrens

**FREEDOM OF INFORMATION REQUEST FOI 5304**

**Notice of Decision**

1. I refer to your request dated 16 July 2024 under the *Freedom of Information Act 1982* (the FOI Act) to the Department of Health and Aged Care for access to the following documents:

*'...the mortality rates associated with Pfizer's BioNTech, also known as (BNT162b2), and Moderna's Spikevax also known as (elasomeran) from 16 July 2020 to 16 July 2024.'*

**Decision Maker**

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

**Decision**

3. Unfortunately, I am unable to continue to process your request because the documents you have requested 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. Despite a thorough and complete search, the documents you have requested do not exist. In these circumstances, section 24A of the FOI Act states that an agency is able to refuse (discontinue processing) the request. Specifically, section 24A states:

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

5. 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 documents requested. However, the documents you have requested do not exist.
6. The reasons the documents you have requested do not exist is because the TGA does not generate documents that contain the 'mortality rates' for all Australians who have been exposed to the specified COVID-19 vaccines. The TGA collects spontaneous adverse event data, which includes reports of death in people who have been vaccinated. Information on deaths reported in clinical trials can be found in the corresponding publicly available AUSPAR and Product Information for each vaccine, in addition to adverse event reports on the Database of Adverse Event Notifications (DAEN) – medicines. However, the TGA does not collect data on general mortality in

Australia or on individuals' vaccination status. As such, the TGA does not hold documents with mortality rates for particular vaccines.

### **Review and Complaint Rights**

7. If you are not satisfied with this decision, you can either seek internal review or apply to the Office of the Australian Information Commissioner (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](http://www.oaic.gov.au/freedom-of-information/your-freedom-of-information-rights/freedom-of-information-reviews).
8. If you have any queries regarding this matter, please contact the FOI Team via email at [TGAFOI@health.gov.au](mailto:TGAFOI@health.gov.au) or telephone (02) 6289 4630.

Yours sincerely

*Authorised and electronically signed by*

Dr Claire Larter  
A/g Assistant Secretary  
Pharmacovigilance Branch  
Therapeutic Goods Administration  
15 August 2024