



Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-3386086

Mr Dan Q

By email: foi+request-7970-a8bff942@righttoknow.org.au

Dear Dan

FREEDOM OF INFORMATION REQUEST FOI 3232
Estimate of Charges

I refer to your request dated 17 October 2021 under the *Freedom of Information Act 1982 (the FOI Act)* for access to the following documents:

"I am writing to request the reviews the TGA has conducted of reports received of deaths in people vaccinated with COVID-19 vaccines.

Please note that for the purposes of this request:

- 1. I am requesting the reviews the TGA has undertaken of reported deaths of individuals vaccinated with COVID-19 vaccines.*
- 2. I wish to limit this request to reviews the TGA has conducted of all such deaths that were reported to the TGA between the 1st and 7th of August 2021 (inclusive) of individuals vaccinated with COVID-19 vaccines.*

If no such deaths of this criteria were reported within that date range, then I revise the date range requested to the next earliest date where such death has been reported to and including such deaths reported in the six days from that date.

- 3. I am requesting for any personally identifiable information to be redacted, or removed where applicable, to enable the provision of the requested documents."*

On 28 October 2021, I informed you of my intention to refuse your request on the basis that a practical refusal reason existed with respect to your request. I also invited you to revise the scope of your request.

On 11 November 2021, you revised the scope of your request as follows:

"I am requesting one (1) review the TGA has performed of a reported death of an individual vaccinated with a COVID-19 vaccine reported to the TGA on 1 August 2021. I request that any one (1) such review performed on such reports made on this date is provided."

On 26 November 2021, the TGA wrote to you to you (via email) and provided you with publicly available information relevant to your request.

On 30 November 2021, you wrote to the TGA stating that:

"In respect of my revised request as outlined in my previous email, can the TGA provide documents evidencing and confirming the review that the TGA performed; and which confirm the documents TGA reviewed in that process?"

Documents not authored by TGA which contain sensitive information may be excluded from this request as it is the TGA's own review of information, the documents which show what the TGA has done in order to conduct its review of the report received, that is the subject of this request."

Under the *Freedom of Information (Charges) Regulations 2019* (the Regulations), a charge can be imposed in respect of a request for access to documents under the FOI Act. The charge is for the search and retrieval of documents, decision making and provision of access (for example, copying and postage).

I am an authorised decision maker under section 23 of the FOI Act, and I have decided that you are liable to pay a charge in respect of the processing of your request for access.

A search and retrieval of documents relevant to your request has been undertaken and a preliminary estimate of charges has been calculated. It is set out in the table below.

1. Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	3.00 hours @ \$15.00 per hour	\$45.00
2. Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	4.30 hours @ \$20.00 per hour Less first 5 hours which are free	\$0.00
3. Postage charges		\$0.00
TOTAL		\$45.00
Deposit required		\$20.00

Under the Regulations, where a charge is imposed and exceeds \$25.00 but is less than \$100.00, a deposit of \$20.00 may be sought. Based on the preliminary estimate of charges for your request, which is \$45.00, I have decided you are required to pay a deposit of \$20.00. Details of payment methods are outlined below.

Under subsection 29(1) of the FOI Act, I am required to notify you that you have 30 calendar days from receipt of this notice to do one of the following:

- pay the charge, being the deposit outlined above, and notify the FOI Team via the email below; or
- notify the TGA that you wish to contend that:
 - the charge has been wrongly assessed, giving reasons; or
 - the charge should be reduced or not imposed (for instance, where payment of the charge would cause you financial hardship or where you believe access to documents is in the general public interest), with reasons; or
- notify the TGA that you withdraw your request.

Please note, should you seek a reduction or waiver of charges on the grounds of financial hardship it would assist the decision maker considering your request if you provide suitable evidence of financial hardship (for example, by providing evidence of receipt of a pension or income support payment; or provide evidence of income, debts or assets). This

is consistent with the FOI Guidelines <https://www.oaic.gov.au/freedom-of-information/foi-guidelines/part-4-charges-for-providing-access>. Evidence should be provided at the time of seeking waiver or reduction.

If you fail to notify the TGA within 30 days about what you propose to do, the FOI Act provides under subsection 29(2) that you are taken to have withdrawn your request.

Timeframes

The time limit for processing your request is suspended, in accordance with section 31 of the FOI Act, from the date you receive this notice and resumes on the day you pay the charge or deposit (including any reduced charge or deposit), or the day on which the TGA makes a decision not to impose a charge.

Once your FOI request has been processed, the TGA will determine the actual charge you must pay before the documents can be provided to you. The final charge for processing your request may be different from the estimate quoted in this letter. If I decide to grant full access to all the documents within the scope of your request, you must pay the actual charges for the time and disbursements involved in processing your request ascertained in accordance with the table set out above (which may be greater or less than the estimate). However, if you are only granted partial access to the documents you will only be required to pay whichever amount is the lesser of the estimate quoted in this letter and the actual charges.

Please note that the decision maker can make a decision to charge for search and retrieval that the TGA has already undertaken for the purposes of your request in its current form, but it may be possible to reduce the decision making and photocopying charges that might be incurred by the TGA in the future if you refine the scope of your request, for example, by limiting the date range of documents sought or excluding a particular category of documents.

If you agree to pay the charge, you are accepting liability for settlement of the debt upon completion of processing the FOI request. Once your FOI request has been processed, the outstanding amount of the charge becomes a debt to the Commonwealth. The TGA is obliged to pursue recovery of the debt in accordance with the *Public Governance, Performance and Accountability Act 2013*.

Payment

If you accept liability for the estimated charge for your request, payment can be made via one of the following options:

- **Credit card payment:**
Complete the credit card payment authorisation form provided with this correspondence
- **Electronic Funds Transfer:**
Payment can be made in the form of electronic funds transfer to the following account:

Bank: Commonwealth Bank of Australia
Account Name: Therapeutic Goods Administration
BSB: 062909
Account: 10215498
- **Cheque:**
Please make cheques payable to Therapeutic Goods Administration, and post to

FOI Coordinator
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Please include reference to FOI 3232 in all forms of payment.

IMPORTANT: Once payment has been made, please notify the FOI Team via the following email address: TGA.FOI@tga.gov.au.

Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

In the event your request relates to documents that include information about a person or their business or professional affairs or about the business, commercial or financial affairs of an organisation or undertaking, pursuant to section 27 and 27A of the FOI Act the TGA will be required to provide that person or organisation the opportunity to make submissions if it appears that they may wish to argue any document is exempt from release.

The statutory time limit for processing an FOI request will be extended by 30 days under subsection 15(6) of the FOI Act where a third party is to be consulted.

If you require clarification of any of the matters discussed in this letter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

Elsbeth Kay
Assistant Secretary
Pharmacovigilance Branch
Therapeutic Goods Administration
30 November 2021