



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 25-0029
Estimate of Charges

1. I refer to your request dated 18 September 2024 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:

'Under the FOI Act 1982, we seek access to the SAS - Category A data set, the SAS - Category B data set and the SAS - Category C data set held by the TGA for the following medicines: triclabendazole, ibrexafungerp, flucytosine, diethylcarbamazine, levofloxacin and fumagillin. We understand that all patient and prescriber information will not be provided.

The routes of administration for the medicines we are interested in are as follows.

*triclabendazole – IV and oral
ibrexafungerp – IV and oral
flucytosine – IV and oral
diethylcarbamazine – IV and oral
levofloxacin – IV and oral
fumagillin – IV and oral*

The timeframe for the request is from 1 January 2017 to 31 December 2023.'

2. 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.
3. 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.

4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	5.00 hours @ \$15.00 per hour	\$75.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	2.75 hours @ \$20.00 per hour Less first 5 hours which are free	\$0.00
TOTAL		\$75.00
Deposit required		\$20.00

5. 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 \$75.00, I have decided you are required to pay a deposit of \$20.00. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.

11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Billers Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 25-0029 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. 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

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s22

Business Improvement and Compliance Section
International Regulatory Branch
Therapeutic Goods Administration
27 September 2024



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

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Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 25-0031
Estimate of Charges

1. I refer to your request dated 18 September 2024 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:

In accordance with the Freedom of Information Act 1982, please provide me with a copy of the following, or allow for their inspection:

- A copy of TGA Adverse Event Notifications for s22 for the period 2000 to 2012.
- A copy of correspondence between the TGA and my client in the period s22 to date, if any.
- Device incident report/s relating to my client's adverse event on about s22, if any.
- Any summary documents of the recall for s22.

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	7.00 hours @ \$15.00 per hour	\$105.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	16.13 hours @ \$20.00 per hour Less first 5 hours which are free	\$222.50
TOTAL		\$327.50
Deposit required		\$81.88

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$327.50, I have decided you are required to pay a deposit of 25 percent, being \$81.88. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).

14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
- '**Billers Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

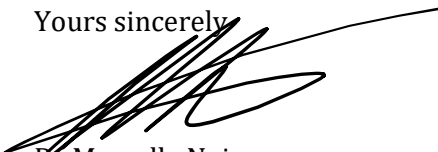
Please include reference to FOI 25-0031 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. If you require clarification of any of the matters discussed in this letter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely



Dr Marcelle Noja
Assistant Secretary
Medical Devices Surveillance Branch
Therapeutic Goods Administration
30 September 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 25-0025
Estimate of Charges

1. I refer to your request dated 17 September 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

'Under the FOI Act 1982, I seek access to copies of the breakdown of the number of requests for scans under the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) for categories A, B or C using the following products.

- *F18\18F-DCFPyL Prostate Specific Membrane Antigen (PSMA)*
- *Gallium 68 Prostate Specific Membrane Antigen (PSMA)*
- *F18\18F-Prostate Specific Membrane Antigen (PSMA)-1007*
- *Technetium-99m Prostate Specific Membrane Antigen (99mTc-PSMA)*
- *PSMA-11 (Prostate Specific Membrane Antigen)*
- *Gallium 68 (Ga 68) Dotatate (aka. 68Ga DOTA peptide PET).'*

The timeframe of this request is from 1 January 2021 to 17 September 2024.

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	2 hours @ \$15.00 per hour	\$30.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing	10.70 hours @ \$20.00 per hour Less first 5 hours which are free	\$114.08

the decision and preparing any documents for release)

TOTAL	\$144.08
Deposit required	\$36.02

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$144.08, I have decided you are required to pay a deposit of 25 percent, being \$36.02. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.

12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
- '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 25-0025 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.

19. 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 & electronically signed by

s22
s22, Business Improvement & Compliance
International Regulatory Branch
Therapeutic Goods Administration
27 September 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 25-0018
Estimate of Charges

- I refer to your request dated 12 September 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:
'A summary document outlining the revision of product information for innovator s22 relating to safety issues and or adverse events (including boxed warning and revisions of boxed warning) for the period of 1 January 2014 to 11 June 2024.'
- 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.
- 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	3.42 hours @ \$15.00 per hour	\$51.30
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	13.01 hours @ \$20.00 per hour Less first 5 hours which are free	\$160.10
TOTAL		\$211.40
Deposit required		\$52.85

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$211.40, I have decided you are required to pay a deposit of 25 percent, being \$52.85. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
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11. 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 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.
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Payment

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14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 25-0018 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. 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

s22
s22 – Business Innovation and Data Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
24 September 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 25-0019
Estimate of Charges

- I refer to your request dated 12 September 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:
'A summary document outlining the revision of product information for innovator s22, relating to safety issues and or adverse events (including boxed warning and revisions of boxed warning) for the period of 1 January 2014 to 20 June 2024.'
- 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.
- 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	3.42 hours @ \$15.00 per hour	\$51.30
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	10.34 hours @ \$20.00 per hour Less first 5 hours which are free	\$106.73
TOTAL		\$158.03
Deposit required		\$39.51

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$158.03, I have decided you are required to pay a deposit of 25 percent, being \$39.51. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 25-0019 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. 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

s22
s22 – Business Innovation and Data Section
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
24 September 2024



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 25-0012
Estimate of Charges

1. I refer to your request dated 10 September 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

'of the previous versions of the TGA s22 PI and CMI documents, are you able to provide 2019-to the version before the current published (April 2024)?'

The timeframe for your request is from 1 January 2019 to 31 July 2024.

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	0.75 hours @ \$15.00 per hour	\$11.25
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	7.62 hours @ \$20.00 per hour Less first 5 hours which are free	\$52.42
TOTAL		\$63.67
Deposit required		\$20.00

5. 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 \$63.67, I have decided you are required to pay a deposit of \$20.00. Details of how to make a payment are outlined below.

6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).

14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:

- '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
- '**Client Identification Number**', enter '**CO-9001**'.
- '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
- '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
- '**Amount (AUD)**', enter the amount of the payment being made.
- '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 25-0012 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.

16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.

18. 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.

19. 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

Andrew Simpson
Assistant Secretary
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
19 September 2024



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

s22
s22
Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 25-0002
Estimate of Charges

1. I refer to your request dated 2 September 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

'I would like to request Freedom of Information on the approvals given by The TGA to use Sodium Thiosulfate (Thiosulphate) under The Special Access Scheme and The Authorised Prescriber Scheme.

Information requested

Date: Approvals granted from 01/12/2023 to 30/06/2024

Product: Sodium Thiosulfate (Thiosulphate) Injection/Vial

Strength: All Strengths

Diagnosis

Indication

Trade Name of Product

Sponsor/Supplier

Expected duration of treatment

Prescriber Speciality

In addition, I also request the number of applications to supply under The Special Access Scheme and The Authorised Prescriber Scheme that have been rejected and the reason for the rejection, from 01/12/2023 to 30/06/2024.'

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	1.5 hours @ \$15.00 per hour	\$22.50
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	8.24 hours @ \$20.00 per hour Less first 5 hours which are free	\$64.88
TOTAL		\$87.38
Deposit required		\$20.00

5. 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 \$87.38, I have decided you are required to pay a deposit of \$20.00. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.

11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 25-0002 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.

18. 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.
19. 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

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s22

, Business Improvement and Compliance Section
International Regulatory Branch
Therapeutic Goods Administration
11 September 2024



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5361
Estimate of Charges

1. I refer to your request dated 23 August 2024 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:

'May I please request the following document:

- s22 "complaint summary.xlsx"

2. 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.
3. 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
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	0.25 hours @ \$15.00 per hour	\$3.75
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	9.12 hours @ \$20.00 per hour Less first 5 hours which are free	\$82.48
TOTAL		\$86.23
Deposit required		\$20.00

5. 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 \$86.23, I have decided you are required to pay a deposit of \$20.00. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

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14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

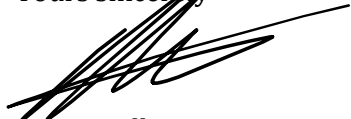
Please include reference to FOI 5361 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. If you require clarification of any of the matters discussed in this letter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely



Dr Marcelle Noja
 Assistant Secretary
 Medical Devices Surveillance Branch
 Therapeutic Goods Administration
 30 September 2024



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5351
Estimate of Charges

1. I refer to your request dated 19 August 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:
*“Therapeutic Goods Administration: Advisory Committee on Medicines
Minutes of meeting 44; 4 and 5 April 2024
Section B Post-market items
Sodium Valproate
And any associated reports or correspondence considered in the meeting regarding sodium valproate.
The text and source of the request made to the ACM for sodium valproate to be evaluated.”*
2. Under the FOI Act, before a charge is imposed in respect of an FOI request, I am required to notify you of certain matters including the amount of the estimated charge and the grounds upon which you can request that a charge not be imposed. I am writing to notify you of those matters. I note that you have already requested that the charge be waived. However, as I have not yet notified you of the relevant matters, I will separately consider your request for a waiver after you have had an opportunity to consider those matters (which are detailed below) and provide any further submissions or information that you may wish to provide.
3. 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.
4. 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 (however, as noted above, I will consider separately your request that the charge should be waived after you have had an opportunity to provide any further submissions or information).
5. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	0.75 hours @ \$15.00 per hour	\$11.25
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	38.86 hours @ \$20.00 per hour Less first 5 hours which are free	\$677.13
TOTAL		\$688.38
Deposit required		\$172.10

6. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$688.38, I have decided you are required to pay a deposit of 25 percent, being \$172.10. Details of how to make a payment are outlined below.
7. 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.
8. 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 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.
9. 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

10. 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.
11. 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.

12. 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 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.
13. 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

14. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
15. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5351 in your payment.

16. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
17. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

18. 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.
19. 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.
20. 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:

Dr Claire Larter
Acting Assistant Secretary
Pharmacovigilance Branch
Therapeutic Goods Administration
11 September 2024



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5348
Estimate of Charges

1. I refer to your request dated 17 August 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:
'I request access to the following documents under the Freedom of Information Act 1982:
1. Summary of all payments received from Pfizer, AstraZeneca, and Moderna from 1 July 2019 to 1 July 2024. The summary should be itemised by financial year.'
2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	5.00 hours @ \$15.00 per hour	\$75.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	7.76 hours @ \$20.00 per hour Less first 5 hours which are free	\$55.28
TOTAL		\$130.28
Deposit required		\$32.57

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$130.28, I have decided you are required to pay a deposit of 25 percent, being \$32.57. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5348 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. If you require clarification of any of the matters discussed in this letter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Electronically authorised and signed by

s22

s22

Regulatory Engagement Branch
Therapeutic Good Administration
28 August 2024



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s22
s22
s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5350
Estimate of Charges

1. I refer to your request dated 16 August 2024 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:

'Documents in the possession of the office of the Deputy Secretary and/or the Chief Medical Advisor since 1 January 2024 that relate to the causes -- known, suspected or speculated -- of shortages of intravenous (IV) fluid products in Australia.'

The timeframe of the request is from 1 January 2024 to 16 August 2024.

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	11 hours @ \$15.00 per hour	\$165.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	36.59 hours @ \$20.00 per hour Less first 5 hours which are free	\$631.78
TOTAL		\$796.78
Deposit required		\$199.20

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$796.78, I have decided you are required to pay a deposit of 25 percent, being \$199.20. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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.

Background

9. On 16 August 2024, the TGA received a request from you under the FOI Act, as follows:

'Documents created or received by the TGA since 1 January 2024 that relate to the causes -- known, suspected or speculated -- of shortages of intravenous (IV) fluid products in Australia.'
10. As part of your application, you advised that you *'do not seek access to duplicates of any document captured within the scope of the request; nor the mobile numbers or full email addresses of government officials, nor the names and contact details of government officials not in the Senior Executive Service or equivalent.*
- I do ask that junior officials' positions or titles be left unredacted, along with email domains that provide useful information as to the origin and destination of communication e.g. '[redacted]@tga.gov.au'.*
11. On 28 August 2024, the TGA wrote to you to advise that *'the relevant line area responsible for searching relevant documents has advised that the scope is currently quite broad and that it would require extensive third party consultation. Where an FOI request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with all affected third parties and provide them an opportunity to make submissions regarding the release of their information...'*
12. A refined scope was provided for your consideration, as follows:

'Correspondence between the TGA and sponsors of Australian registered intravenous (IV) fluid products since 1 January 2024 that relates to the causes -- known, suspected or speculated -- of shortages of intravenous (IV) fluid products in Australia.'

13. It was also suggested that you may wish to reduce the timeframe of your request further to increase the likelihood of the search and retrieval being more manageable, however, as noted, this was provided for your consideration.
14. On 29 August 2024, you revised the scope of your request, as reflected in paragraph one, above.
15. On 30 August 2024 and following receipt, you confirmed the TGA's interpretation of your scope to be for documents in the possession of the office of Deputy Secretary of the TGA and or the Chief Medical Advisor of the TGA.
16. On 9 September 2024, you excluded documents relating to media requests from the scope of the request.
17. On 16 September 2024, you agreed to a 12-day extension under s15AA of the FOI Act for the processing of your request.
18. On 20 September 2024, you confirmed that you do not seek access to draft documents:
'I do not seek drafts, unless there is no final, in which case I only want the latest draft.'

Timeframes

19. 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.
20. 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.
21. 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 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.
22. 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

23. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
24. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:

- **'Biller Code'**, click on the drop-down arrow to select option **'11 – Freedom of Information (FOI)'**.
- **'Client Identification Number'**, enter **'CO-9001'**.
- **'Reference Number'**, enter your unique FOI identification number followed by your first and last name (e.g. **'FOI-XXXX John Smith'**).
- **'Email Address for Tax Receipt'**, enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
- **'Amount (AUD)'**, enter the amount of the payment being made.
- **'Select your payment option'**, click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5350 in your payment.

25. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
26. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

27. 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.
28. 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.
29. 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

s22 [REDACTED]
s22 [REDACTED] to the Deputy Secretary
Therapeutic Goods Administration
24 September 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22

s22

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5343
Estimate of Charges

- I refer to your request dated 16 August 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:
Ministerial submissions and briefings provided by the Department to the Minister for Health and Care, the Hon Mark Butler MP since 1 January 2024 that relate to shortages in Australia of intravenous (IV) fluid products.
- 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.
- 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	4.75 hours @ \$15.00 per hour	\$71.25
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	17.29 hours @ \$20.00 per hour Less first 5 hours which are free	\$245.77
TOTAL		\$317.02
Deposit required		\$79.25

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$317.02, I have decided you are required to pay a deposit of 25 percent, being \$79.25. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5343 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. 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

Dr Claire Larter
 Acting Assistant Secretary
 Pharmacovigilance Branch
 Therapeutic Goods Administration
 20 September 2024



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5298
Estimate of Charges

1. I refer to your request dated 25 July 2024 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:
'In relation to Infanrix Hexa, any clinical or non-clinical evaluation report (or summary of submitted data) relating to the approval to vary clinical aspects of the Product Information documents in June 2006.'
2. The below estimate is based on the data provided by the sponsor of the medicine in relation to its application to update the Product Information for Infanrix Hexa in 2006. Specifically, we have identified the *Common Technical Document Summary*, which provides a detailed overview of all evidence provided to the TGA to support this submission (including clinical trials). The document is 473 pages and has been digitised from hard copy files.
3. 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.
4. 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.
5. A preliminary estimate of charges has been calculated. It is set out in the table below.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	10 hours @ \$15.00 per hour	\$150.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	9 hours @ \$20.00 per hour Less first 5 hours which are free	\$87.38
TOTAL		\$237.38

Deposit required	\$59.35
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6. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$237.38, I have decided you are required to pay a deposit of 25 percent, being \$59.35. Details of how to make a payment are outlined below.
7. 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.
8. 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 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.
9. 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.

Background

s22



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Timeframes

34. 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.
35. 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.
36. 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 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.
37. 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

38. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
39. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5298 in your payment.

40. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for

1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.

41. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

42. 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.
43. 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.
44. 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

Andrew Simpson
Assistant Secretary
Prescription Medicines Branch
Therapeutic Goods Administration
24 September 2024



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5280
Estimate of Charges

1. I refer to your request dated 15 July 2024 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:

'Under the FOI Act 1982, I seek access to a copy of the Public Assessment Report on Wegovy which is a semaglutide drug manufactured by Novo Nordisk.

Under the FOI Act 1982, I seek access to a copy of the most recent Public Assessment Report on semaglutides.

Under the FOI Act 1982 I seek access to documents relating to the decision making approval of Wegovy (a semaglutide) by the TGA.'

Scope clarification as at 22 July 2024:

I am seeking the Public Assessment Report on Wegovy

I am seeking the Delegates Overview and the Clinical Evaluation report and Non Clinical Evaluation report for Wegovy

I am seeking documents for both the original registration of Wegovy plus the extension of indication for use in adolescents.'

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	4.00 hours @ \$15.00 per hour	\$60.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	8.56 hours @ \$20.00 per hour Less first 5 hours which are free	\$71.28
TOTAL		\$131.28
Deposit required		\$32.82

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$131.28, I have decided you are required to pay deposit of 25 percent, being \$32.82. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.

11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5280 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.

18. 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.
19. 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

s22

Acting Assistant Secretary
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
29 July 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22
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s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 25-0003
Estimate of Charges

1. I refer to your request dated 3 September 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:
'Documents containing information on the number of units of unregistered medicinal cannabis products supplied for the period 1/1/2024-30/6/2024, taken from the six-monthly reports submitted by product sponsors, as required under regulation 47B(1)(c) of the Therapeutic Goods Regulations 1990. This should contain the same level of detail as the information released in FOI 4712 (date of release 16/10/2023), being:
 - a) *The number of units supplied for each product – not grouped in any way*
 - b) *Specifying the number of units supplied via either SAS or AP approval pathways – for each product*
 - c) *With products identified only by their medicinal cannabis product Category (1-5) and format (oral oil, herb dried for inhalation etc.).'*
2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	1.50 hours @ \$15.00 per hour	\$22.50
Decision making time (including time spent examining the documents, considering exemptions,	4.64 hours @ \$20.00 per hour Less first 5 hours which are free	\$0.00

undertaking consultation, writing the decision and preparing any documents for release)

TOTAL	\$22.50
Deposit required	\$22.50

5. Under the Regulations where a charge is imposed and is less than \$25.00, the full amount may be sought. Based on the preliminary estimate of charges for your request which is \$22.50, I have decided you are required to pay the full amount of \$22.50. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.

12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 25-0003 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.

19. 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

s22 [REDACTED]
s22 [REDACTED], Business Improvement & Compliance Section
International Regulatory Branch
Therapeutic Goods Administration
17 September 2024



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5353
Estimate of Charges

1. I refer to your request dated 16 August 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

'...1. A list of the DAEN notifications of the 1004 deaths notified to you as declared at in the "COVID vaccine safety report 2/11/23" at the below link. The list should include the DAEN reference, vaccine reported, date of death and date of notification.

<https://www.tga.gov.au/news/covid-19-vaccine-safety-reports/covid-19-vaccine-safety-report-02-11-23>

2. A summary of the death notification totals by 10 year age groups (buckets) and vaccine type administered (Pfizer, Moderna, Other)...
2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	2.50 hours @ \$15.00 per hour	\$37.50
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	4.47 hours @ \$20.00 per hour Less first 5 hours which are free	\$0.00
TOTAL		\$37.50
Deposit required		\$20.00

5. 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 \$37.50, I have decided you are required to pay a deposit of \$20.00. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
 14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Billor Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.
- Please include reference to FOI 5353 in your payment.**
15. If you require assistance with making a payment, please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
 16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.
 17. 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

Dr Claire Larter
A/g Assistant Secretary
Pharmacovigilance Branch
Therapeutic Goods Administration
10 September 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5360
Estimate of Charges

1. I refer to your request dated 13 August 2024 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:

'(1) The case number and age (years) of all adverse event reports (AERs) in the Adverse Event Management System (AEMS) where one or more non-COVID-19 vaccines have been listed as a suspected medicine WHERE DEATH WAS A REPORTED OUTCOME. This includes AERs where both one or more non-COVID-19 vaccines have been listed as a suspected medicine AND one or more one or more COVID-19 vaccines have been listed as a suspected medicine. This request relates to the period from 1/1/1971 to 14/8/2024 or the date of extraction, whichever is later. The date range boxes did not allow 1971 to be selected.

(2) The raw data for the time between the most recent non-covid vaccination and death. This does not have to be linked directly to the above data and can be a single column of data however it is requested that the data for all deaths is provided (ie the overall number of deaths should match) and that there is an entry for cases where the time between the most recent non-covid vaccination and death is unknown. This request relates to the period from 1/1/1971 to 14/8/2024 or the date of extraction, whichever is later. The date range boxes did not allow 1971 to be selected.

(3) The raw data for the time between the most recent covid-19 vaccination and death for all adverse event reports in the Adverse Event Management System (AEMS) where one or more COVID-19 vaccines have been listed as a suspected medicine and WHERE DEATH WAS A REPORTED OUTCOME.

It is requested that the data for all deaths is provided and that there is an entry for cases where the time between the most recent covid-19 vaccination and death is unknown.

This request relates to the period from 1/12/2020 to 14/8/2024 or the date of extraction, whichever is later.'

Scope clarified 26/8.

'...By "raw data", I mean the calculated time between: (1) the most recent non-covid-19 vaccination and death; and (1) most recent covid-19 vaccination and death. For example: 1 day, 32 days, unknown. I am not requesting any dates...'

'...I only want cases where non-covid 19 vaccines were listed as a suspected medicine. I do not want cases where other medicines were listed as suspected medicines, where no non-covid vaccines was listed as suspected medicines...'

Scope clarified 29/8.

'I am specifically wanting all adverse event reports in the AEMS where one or more non-covid vaccines have been listed as a suspected medicine as I am wanting the AEMS ages which can differ to the DAEN for some cases. I am also interested in the number of cases in the AEMS not listed in the DAEN. This is something I can work out for myself. If I have any questions about these, I will submit a follow up FOI...'

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	4.00 hours @ \$15.00 per hour	\$60.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	5.81 hours @ \$20.00 per hour Less first 5 hours which are free	\$16.25
TOTAL		\$76.25
Deposit required		\$20.00

5. 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 \$76.25, I have decided you are required to pay a deposit of \$20.00. Details of how to make a payment are outlined below.
6. 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.

7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Bill Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit

payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.

- **'Amount (AUD)'**, enter the amount of the payment being made.
- **'Select your payment option'**, click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5360 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. 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

Dr Claire Larter
A/g Assistant Secretary
Pharmacovigilance Branch
Therapeutic Goods Administration
9 September 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5358
Estimate of Charges

1. I refer to your request dated 13 August 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

'(1) The case number and age (years) of all adverse event reports (AERs) in the Adverse Event Management System (AEMS) where one or more non-COVID-19 vaccines have been listed as a suspected medicine. This includes AERs where both one or more non-COVID-19 vaccines have been listed as a suspected medicine AND one or more one or more COVID-19 vaccines have been listed as a suspected medicine. This request relates to the period from 1/1/1971 to 14/8/2024 or the date of extraction, whichever is later. The date range boxes did not allow 1971 to be selected.

(2) The case number and age (years) of all adverse event reports (AERs) in the Adverse Event Management System (AEMS) where one or more COVID-19 vaccines have been listed as a suspected medicine. This request relates to the period from 1/12/2020 to 14/8/2024 or the date of extraction, whichever is later.'

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	2.00 hours @ \$15.00 per hour	\$30.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	5.68 hours @ \$20.00 per hour Less first 5 hours which are free	\$13.50
TOTAL		\$43.50
Deposit required		\$20.00

5. 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 \$43.50, I have decided you are required to pay a deposit of \$20.00. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).

14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
- '**Bill Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.
- Please include reference to FOI 5358 in your payment.**
15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. 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

Dr Claire Larter
A/g Assistant Secretary
Pharmacovigilance Branch
Therapeutic Goods Administration
10 September 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5317
Estimate of Charges

1. I refer to your request dated 3 August 2024 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:

'A data table that includes AP and SAS approvals and notifications for dalbavancin, including the dosage form, dosage and frequency of use for dalbavancin.'

The timeframe for your request is from 1 January 2021 to 30 June 2024.

2. 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.
3. 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.
4. 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.

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
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	4.19 hours @ \$20.00 per hour Less first 5 hours which are free	\$0.00
TOTAL		\$45.00
Deposit required		\$20.00

5. Under the Regulations where a charge is imposed 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 how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5317 in your payment.

15. If you require assistance with making a payment, please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. 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

s22
s22, Business Improvement and Compliance Section
 International Regulatory Branch
 Therapeutic Goods Administration
 9 August 2024



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5310
Estimate of Charges

1. I refer to your request dated 31 July 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

s22

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	4.00 hours @ \$15.00 per hour	\$60.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	20.68 hours @ \$20.00 per hour Less first 5 hours which are free	\$313.58
TOTAL		\$373.58
Deposit required		\$93.40

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$373.58, I have decided you are required to pay a deposit of 25 percent, being \$93.40. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5130 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. If you require clarification of any of the matters discussed in this letter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Electronically authorised and signed by

s22
s22

Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
7 August 2024



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5308

Estimate of Charges

1. I refer to your request dated 29 July 2024 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:

'For the time period January 2017 to December 2023 (7 year period), please provide the name and number of applications for each unregistered antimicrobial obtained via the Special Access Scheme. Please provide the number of applications for each drug per month, for each of the SAS categories, by State/Territory.'

Scope clarified 29 July 2024

'We specifically request access to the SAS - Category A data set, the SAS - Category B data set and the SAS - Category C data set held by the TGA for the antimicrobials listed in the attached document. We understand that all patient and prescriber information will not be provided.'

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	6.25 hours @ \$15.00 per hour	\$93.75
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	5.87 hours @ \$20.00 per hour Less first 5 hours which are free	\$17.42
TOTAL		\$111.17
Deposit required		\$27.79

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$111.17, I have decided you are required to pay a deposit of 25 percent, being \$27.79. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.

11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5308 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.

18. 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.
19. If you require clarification of any of the matters discussed in this letter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Electronically authorised and signed by

s22
s22

, Business Improvement and Compliance Section
International Regulatory Branch
Therapeutic Goods Administration
7 August 2024



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5293

Estimate of Charges

1. I refer to your request dated 19 July 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

'List of Batch Numbers (and doses) for all COVID-19 vaccine adverse event reports which are included in the DAEN – medicines (date range 21 December 2020 to 5 July 2024)

List of 'serious' cases for all COVID-19 vaccine adverse event reports which are included in the DAEN – medicines (date range 21 December 2020 to 5 July 2024)'

Interpretation of Request

2. I note from your email to the TGA FOI team dated 19 July 2024 that you are seeking to have the data presented in a specific format. Please note that while we can accommodate an excel document as requested, it may not be possible to format the data in the specific way you have requested. The format you have requested would require a bespoke presentation of the data. The work involved in assessing and manipulating the data may represent an unreasonable diversion of resources and therefore, your request would not be processable. Instead, we can provide the data in the format in which it is extracted from the database, and the estimated charges are based on this format.

Estimate of Charges

3. 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.
4. 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.
5. 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.

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
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	8.01 hours @ \$20.00 per hour Less first 5 hours which are free	\$60.17
TOTAL		\$105.17
Deposit required		\$26.29

6. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$105.17, I have decided you are required to pay a deposit of 25 percent, being \$26.29. Details of how to make a payment are outlined below.
7. 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.
8. 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 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.
9. 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

10. 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.
11. 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.

12. 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 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.
13. 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

14. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
15. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5293 in your payment.

16. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
17. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

18. 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.
19. 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.
20. 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

Dr Claire Larter
Acting Assistant Secretary
Pharmacovigilance Branch
Therapeutic Goods Administration
9 August 2024



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

s22
 Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5286
Estimate of Charges

1. I refer to your request dated 18 July 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

'I am writing to request under for Freedom of Information Act, the following documents:

- 1. The standard operating procedure (SOP) or protocol for assessing the presence of residual DNA in the mRNA COVID vaccine products provisionally approved by the TGA.*
- 2. The document showing evidence of the TGA's claim in your email communication to me dated 20 June 2024: "There is no significance to minute amounts of residual DNA being encapsulated in the LNPs.". This should include evidence of any in-situ hybridisation experiments conductions by the TGA, and/or genotoxicity assessments and/or long term carcinogenicity data and/or an expert panel committee meeting minutes which identify the experts that have contributed to this statement.*
- 3. The document underpinning your claim in your communication to me on 20 June 2024 that "There is no accepted science that shows any alteration of the human genome," that includes an assessment of the Alden and Jaenisch papers showing reverse transcription of mRNA to DNA and the TGA's assessment of nuclear localisation of mRNA and/or spike protein.'*

The timeframe of the request is from 1 June 2019 to 30 June 2024.

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	0.25 hours @ \$15.00 per hour	\$3.75
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Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	9.01 hours @ \$20.00 per hour Less first 5 hours which are free	\$80.17
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TOTAL	\$83.92
Deposit required	\$20.00

5. 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 \$83.92, I have decided you are required to pay a deposit of \$20.00. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.

11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11-digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5286 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.

18. 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.
19. 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

s22

A/g Assistant Secretary
Laboratories Branch
Therapeutic Goods Administration
31 July 2024



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s22

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5285
Estimate of Charges

1. I refer to your request dated 15 July 2024 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:

I am writing to request under the Freedom of Information Act the following documents in relation to the product "Nuvaxovid" assessed in the TGA AusPAR documented at <https://www.tga.gov.au/sites/default/files/auspar-sars-cov-2-rs-matrix-m-adjutant.pdf>

1. *The TGA non-clinical evaluation report for this product (redactions should be severely limited to only phrases that are specifically required to protect proprietary information that is not in the public domain).*
 2. *A printout of the test results in the testing database and any other documents we hold that refer to residual DNA for the specified batches', for the following batches: 4302MF021, 4302MF011, 4301MF005, 4301MF004. The reports should specifically include an assessment of DNA and/or plasmid levels in the product which should not be redacted.*
 3. *The SOP (standard operating procedure or lab protocol) for the analysis of the batch assessment reports for the analyses specified in (2) and required by the TGA of the laboratory conducting the batch assessments.*
 4. *The plasmid map supplied by the sponsor to the TGA.*
2. 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.
 3. 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.
 4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	8.00 hours @ \$15.00 per hour	\$120.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	22.14 hours @ \$20.00 per hour Less first 5 hours which are free	\$342.80
TOTAL		\$462.80
Deposit required		\$115.70

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$462.80, I have decided you are required to pay a deposit of 25 percent, being \$115.70. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.

11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5285 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. 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

Dr Lisa Kerr PSM PhD MBA
Assistant Secretary
Laboratories Branch
Therapeutic Goods Administration
16 August 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5276
Estimate of Charges

1. I refer to your request dated 10 July 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

I am writing to request under the freedom of information act the following documents in relation to the TGA's approval and pharmacovigilance in relation to Gardasil 4 (2007-2015)

1. *The full report of the TGA investigation of premature ovarian failure reported in relation to Gardasil as described in the TGA's document here*
<https://www.tga.gov.au/news/safety-alerts/gardasil-quadrivalent-human-papillomavirus-vaccine-update-2>
 2. *A list of the reference numbers and description of any deaths reported to the TGA in regard to Gardasil in any of the reporting systems held by the TGA including the DAEN and any other AEFI database*
 3. *A list of batch numbers of Gardasil 4 which underwent batch analysis by the TGA*
 4. *A copy of the standard operating procedure for batch analysis of Gardasil 4 from 2012-2015*
 5. *A copy of any TGA assessment report relating to plasmid contamination of Gardasil 4 conducted at any time following the release of the Lee paper confirming plasmid contamination of Gardasil 4 in 2012 linked here*
<https://pubmed.ncbi.nlm.nih.gov/23078778/>
 6. *Any TGA report relating to the assessment of plasmid or DNA contamination assessment of Gardasil 4 following approval.'*
2. 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.
 3. 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.

4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	10.5 hours @ \$15.00 per hour	\$157.50
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	5.79 hours @ \$20.00 per hour Less first 5 hours which are free	\$15.78
TOTAL		\$173.28
Deposit required		\$43.32

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$173.28, I have decided you are required to pay a deposit of 25 percent, being \$43.32. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.

11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Billers Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5276 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. 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

s22

A/g Assistant Secretary
Laboratories Branch
Therapeutic Goods Administration
02 August 2024



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5255

Estimate of Charges

1. I refer to your request dated 8 July 2024 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:

'...I seek access to copies of data tables relating to Authorised Prescriber and Special Access Scheme Category A and B pathways specific to medicinal cannabis products during the period 01/01/16 to 01/06/24. As well as adverse event reports information, equivalent to the information included in the DAEN – medicines, for adverse event reports where a medicine containing cannabinoids is the suspect or interacting medicine, during the period 01/01/16 to 01/06/2024.

The specific data parameters collected under the SAS scheme I am requesting are:

Submission, Received Date, Application Date, Form Type, Product Type, Previous SAS Number, Decision, Decision date, Duration Of Supply, Patient DOB, Patient Gender, Product profile, Product Presentation, Indication, Dosage Regimen, Strength/Dimensions, Strength Unit, Active Ingredient, SUSMP Schedule, Route of Administration, Cannabis State Application Required, Active Ingredient Category, Practitioner Type, Prescriber Specialty, Consulting Location

The specific data parameters collected under the AP scheme I am requesting are:

Submission, Received Date, Application Date, Withdrawn Date, Expiry Date, Decision date, Decision, Product Type, Duration Of Supply, Medicine with an established history of use, Unapproved Product, Product Presentation, Primary Indication, Endorsing Body, HREC Endorsing indications / reasons, Primary Location^[SEP] (State or Territory), Prescriber Specialty, Reporting Period, Total number of patients, Number of New Patients

I am aware that:

Regarding SAS and AP data: The TGA changed from trade name based medicinal cannabis submissions to category-based submissions on 22/11/2021. Data provided from 1/1/2016 to 21/11/2021 will be based on the schedule of the product, rather than individual trade names. Data from 22/11/2021 to 1/6/2024 will be based on category-based submissions.

Regarding DAEN data: The following Adverse Event data can be provided and is consistent with information within the DAEN and previously processed FOI requests – Case number, Report Entry date, Gender, Age, Medicines reported as being taken and medDRA reaction terms. The date range would be limited to that not previously released under other FOIs.'

2. 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.
3. 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.
4. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	27.5 hours @ \$15.00 per hour	\$412.50
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	5.45 hours @ \$20.00 per hour Less first 5 hours which are free	\$9.03
TOTAL		\$421.53
Deposit required		\$105.38

5. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$421.53, I have decided you are required to pay a deposit of 25 percent, being \$105.38. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.

8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
- '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5255 in your payment.

15. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

17. 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.
18. 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.
19. If you require clarification of any of the matters discussed in this letter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Electronically authorised and signed by

s22 [REDACTED]
s22 [REDACTED] Business Improvement and Compliance Section
International Regulatory Branch
Therapeutic Goods Administration
31 July 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5246
Estimate of Charges

1. I refer to your request dated 3 July 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

'A list of overseas-registered semaglutide products approved for temporary use while the Ozempic registered in Australia is unavailable, including product name, manufacturer, distributor, country where overseas registration was obtained, and other available details about the product

A copy of the registration certificate oversees for each instance of this product's import since approved for temporary use

A copy of export and import certificates for each instance of this product's import since approved for temporary use

A copy of the air waybill for each instance of the products' import since approved for temporary use

A copy of the packaging manifest for each instance of the products' import since approved for temporary use.'

The timeframe for your request is from 1 January 2019 to 3 July 2024.

Background

2. On 3 July 2024, the TGA received a request from you under the FOI Act.
3. On 9 July 2024, you advised that personal information of third parties is excluded from the scope of your request.
4. On 22 July 2024, the TGA wrote to you to advise that the Medicines Shortages Section has been able to compile a table for the purposes of fulfilling part 1 your request, adding that much of the information you have requested in relation to this point is available on the TGA's [Section 19A database](#).
5. On this date, you were also advised that '*...the last three columns of the spreadsheet being 'Product Images', 'Dear Healthcare Professional Letter' and 'Summary of Product Characteristics' contain links (only) to approximately 70 documents containing in excess of 900 pages...*' and your consideration was sought of '*omitting these documents from the scope of your request, however noting that you may at a later date choose to seek access to these individual documents. If you [were] amenable to this, it [was] proposed that the table be provided to you in response to your request, FOI 5246'* and '*In relation*

to the other points of your scope, [the line area] advised that the Australian Border Force would be best placed to assist you...'

6. You responded of even date, advising 'Ok, that is fine, thank you.'
7. 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.
8. 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.
9. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	5 hours @ \$15.00 per hour	\$75.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	12.24 hours @ \$20.00 per hour Less first 5 hours which are free	\$144.88
TOTAL		\$219.88
Deposit required		\$54.97

10. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$219.88, I have decided you are required to pay a deposit of 25 percent, being \$54.97. Details of how to make a payment are outlined below.
11. 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.
12. 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 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.

13. 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

14. 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.
15. 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.
16. 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 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.
17. 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

18. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
19. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
- '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5246 in your payment.

20. If you require assistance with making a payment, please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
21. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

22. 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.
23. 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.
24. 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

Elspeth Kay
Assistant Secretary
Pharmacovigilance Branch
Therapeutic Goods Administration
25 July 2024



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5217
Estimate of Charges

1. I refer to your request dated 27 June 2024 under the *Freedom of Information Act 1982* (the FOI Act) and subsequent correspondence between you and the TGA, including a Request Consultation Period in accordance with section 24AB of the FOI Act, in which the scope of your request was clarified as being for access to the following documents:

'Seeking copies of the s22 infringement notices that were issued to s22 by the TGA.'

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.

2. 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.
3. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	1 hour @ \$15.00 per hour	\$15.00
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	9.94 hours @ \$20.00 per hour Less first 5 hours which are free	\$98.80
TOTAL		\$113.80
Deposit required		\$28.45

4. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$113.80, I have decided you are required to a deposit of 25 percent, being \$28.45. Details of how to make a payment are outlined below.

5. 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.
6. 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 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.
7. 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

8. 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.
9. 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.
10. 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 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.
11. 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

12. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).

13. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
- '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5217 in your payment.

14. If you require assistance with making a payment please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
15. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

16. 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.
17. 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.
18. 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

s22
s22

Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
9 August 2024



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

s22
s22
s22
Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5218
Estimate of Charges

1. I refer to your request dated 25 June 2024 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:

'...all advice provided to the Health Minister since 1 July 2023 and the date of this request on down-scheduling vape products.

...all correspondence to the Health Minister received since 1 January 2024 and held by the Department that contains references to down-scheduling vape products.'

Clarified on 4 July 2024

'...the scope of the request is advice to the Minister and his office.

...correspondence held by the TGA from third parties to the Minister, but I will limit the scope of the request to businesses and special interest groups such as the s22.'

2. 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.
3. 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.
4. 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.

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
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	18.10 hours @ \$20.00 per hour Less first 5 hours which are free	\$261.97
TOTAL		\$333.77
Deposit required		\$83.44

5. Under the Regulations, where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request, which is \$306.97, I have decided you are required to pay a deposit of 25 percent, being \$76.74. Details of how to make a payment are outlined below.
6. 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.
7. 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 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.
8. 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

9. 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.
10. 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.
11. 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 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.
12. 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

13. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
14. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5218 in your payment.
15. If you require assistance with making a payment, please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
16. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third party consultation

17. 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.
18. 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.
19. 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

Mandy Edlington
 A/g Assistant Secretary
 Vaping Legislative Reform Branch
 Therapeutic Goods Administration
 29 July 2024



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

s22

Email: s22

Dear

FREEDOM OF INFORMATION REQUEST FOI 5226
Estimate of Charges

1. I refer to your request dated 24 June 2024 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

I request all communication and documentation, internal and external, that your institution holds related to the following process:

The fining of s22 in response to s22 infringement notices issued by the Therapeutic Goods Administration (TGA) within the Department of Health. s22

- Specifically to be included are the communications received on the matter by

The timeframe for the request is from 1/1/2016 to 31/5/2024.

2. Revised scope provided 25 June 2024:

I would like to narrow down to request to just communication regarding the infringement notices between the TGA and s22 as well as between the TGA and s22.

I would like to narrow down the timeframe to: 1/1/2016 to 31/12/2020.'

3. 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.
4. 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.
5. 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.

Search and retrieval time (including time spent locating relevant files and collating relevant documents	2 hours @ \$15.00 per hour	\$30.00
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contained on those files)		
Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	18.36 hours @ \$20.00 per hour Less first 5 hours which are free	\$267.23
TOTAL		\$297.23
Deposit required		\$74.31

6. Under the Regulations where a charge is imposed and exceeds \$100.00, a deposit of 25 percent may be sought. Based on the preliminary estimate of charges for your request which is \$297.23, I have decided you are required to pay a deposit of 25 percent, being \$74.31. Details of how to make a payment are outlined below.
7. 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.
8. 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 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.
9. 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

10. 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.
11. 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.

12. 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 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.
13. 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

14. Payments for FOI requests must be made online via the TGA's [Online Payment Portal](http://www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal) (www.tga.gov.au/how-we-regulate/fees-and-payments/payment-options/online-payment-portal).
15. To make an FOI payment, you will be required to enter specific information as outlined below. From the Online Payment Portal site, click on the option titled '**Online payment portal**' to display the payment portal page. From the payment portal page, enter the following information:
 - '**Biller Code**', click on the drop-down arrow to select option '**11 – Freedom of Information (FOI)**'.
 - '**Client Identification Number**', enter '**CO-9001**'.
 - '**Reference Number**', enter your unique FOI identification number followed by your first and last name (e.g. '**FOI-XXXX John Smith**').
 - '**Email Address for Tax Receipt**', enter the email address you wish to receive a tax receipt for your payment transaction. This email will contain a unique 11 digit payment transaction number to quote if you have any queries. Please retain this email for your records. A tax invoice will not be issued for this transaction.
 - '**Amount (AUD)**', enter the amount of the payment being made.
 - '**Select your payment option**', click on the relevant icon to proceed to the next screen.

Please include reference to FOI 5226 in your payment.

16. If you require assistance with making a payment, please contact the TGA Accounts team on 1800 020 653 (option 5) or by email at accountsrec@health.gov.au. Users who are deaf or have a hearing or speech impairment can call through the National Relay Service: TTY or computer with modem users: phone 1800 555 677 then ask for 1800 020 653. Speak and listen (speech to speech relay) users: phone 1800 555 727 then ask for 1800 020 653.
17. **IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: TGAFOI@health.gov.au. Failure to notify the FOI Team of payment may result in delays to the processing of your FOI request.

Third Party Consultation

18. 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.

19. 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.
20. 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

Tracey Lutton
Assistant Secretary
Regulatory Compliance Branch
Therapeutic Goods Administration
12 August 2024



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s22
s22
s22

Email: s22

Dear s22

FREEDOM OF INFORMATION REQUEST FOI 5350 Notice of Decision – Request for a waiver of charges

1. I refer to your request dated 16 August 2024 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:

'Documents in the possession of the office of the Deputy Secretary and/or the Chief Medical Advisor since 1 January 2024 that relate to the causes -- known, suspected or speculated -- of shortages of intravenous (IV) fluid products in Australia.'

The timeframe of the request is from 1 January 2024 to 16 August 2024.

Background

2. On 16 August 2024, the TGA received a request from you under the FOI Act.
3. On 24 September 2024, you were advised that the costs associated with processing your request amounted to \$796.78 and you were asked to;
 - pay the charge, being either the deposit or the full amount, and notify the TGA FOI Team; or
 - argue that:
 - the charge was wrongly assessed, providing reasons; or
 - the charge should be reduced or not imposed, providing reasons; or
 - withdraw your request.
4. On 25 September 2024, the TGA received the payment for processing your request in full. In addition, you submitted a request for a waiver of further charges on public interest grounds.

Decision Maker

5. I am the TGA officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Decision

6. I have decided to reduce the charges that can be imposed for the processing of your request by 70%. As the initial estimated charge was \$796.78, the revised estimated charge is \$239.04 with an initial deposit of \$59.76.

Material Considered in Decision-Making

7. In coming to my decision I had regard to the following:
- your request for documents under the FOI Act dated 16 August 2024;
 - my initial decision of 24 September 2024 to impose charges of \$796.78;
 - the correspondence from you of 25 September 2024, requesting that the charges be waived as access to the documents is in the public interest;
 - the FOI Act and, in particular, section 29 of the FOI Act; and
 - the guidelines issued by the Australian Information Commissioner under section 93A of the FOI Act (FOI Guidelines).

Reasons for Decision

8. In considering a request that charges not be imposed, subsection 29(5) of the FOI Act provides:

Without limiting the matters the agency or Minister may take into account in determining whether or not to reduce or not to impose the charge, the agency or Minister must take into account:

- (a) *whether the payment of the charge, or part of it, would cause financial hardship to the applicant, or to a person on whose behalf the application was made; and*
- (b) *whether the giving of access to the document in question is in the general public interest or in the interest of a substantial section of the public.*

9. In addition, Part 4 of the FOI Guidelines sets out the matters I must have regard to in considering a request not to impose a charge.
10. In making this FOI request, you have not made any submissions about your current financial affairs or provided any evidence of financial hardship and have not requested a waiver or reduction of charges on financial hardship grounds.
11. Therefore, currently, there is insufficient evidence for me to be satisfied that payment of the charge would cause you financial hardship.

Public Interest

12. In considering whether granting access to the documents would be in the public interest or in the interest of a substantial section of the public, the FOI Guidelines say it is important to identify the 'general public interest' or the 'substantial section of the public' that would benefit from disclosure.
13. I consider that the documents coming within the scope of your request may be in the general public interest.
14. In considering the public interest, paragraph 4.109 of the FOI Guidelines sets out a non-exhaustive list of examples in which it may be appropriate to reduce or waive a charge. The factors that may be relevant here include the following:
- the document relates to a matter of public debate, or to a policy issue under discussion within an agency, and disclosure will assist public comment on, or participation in, the debate or discussion; and/or
 - The document is to be used by a journalist to prepare a story for publication that is likely to be of general public interest.
15. In your submission you indicated that *"There has been significant interest in this matter in the Federal parliament."* You also state *"There has also been significant media interest in this matter."*

16. I am satisfied that a substantial section of the public may benefit from the disclosure of this information.

Conclusion

17. On the basis that the giving of access to the documents is in the public interest as set out above, I have decided to reduce the charges associated with the processing of your FOI request by 70%.

18. Please note my decision to reduce the charges by 70% will apply to the **final amount** of charges that can be imposed. Under the *Freedom of Information (Charges) Regulations 2019* (the Charges Regulations), once an FOI is complete, the TGA is required to determine the **actual** charges that can be imposed under the Charges Regulations associated with processing the request. This final amount may be higher or lower than the estimated charges.

19. In the event the final charge is less than the estimate, you will be refunded the difference. If the final charges exceed the estimate (and my decision is to give you full access to all relevant information) regulation 10(2) allows me to charge the actual cost (including the 70% reduction). If any information is exempt, a higher amount cannot be imposed.

Time limit for processing your FOI request

20. At decision making stage the actual charges will be calculated. As you have paid the estimate of charges in full, you will be refunded any overpayment.

21. In addition to this, and as detailed in the notice of estimate of charges letter, the time limit for processing your request was suspended, in accordance with section 31 of the FOI Act, from the date you received that notice, which was 24 September 2024. Subsequently, the time limit for processing your request resumed once payment was received, which was 25 September 2024.

22. Further, as your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

23. Accordingly, under section 15(6) of the FOI Act, and upon payment of a deposit, the timeframe for processing your request has been extended by 30 days to allow the consultation process to be conducted.

Review and Complaint Rights

24. 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/

25. If you have any queries regarding this matter, please contact the FOI Team via email at TGAFOI@health.gov.au or telephone (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

s22
s22 to the Deputy Secretary
Therapeutic Goods Administration
3 October 2024

From: [TGA FOI](#)
To: s22 [REDACTED]
Cc: [TGA FOI](#)
Subject: FOI 5280 - Decision on waiver of charges [SEC=OFFICIAL]
Date: Thursday, 1 August 2024 4:12:18 PM
Attachments: [image001.png](#)

Dear s22 [REDACTED],

I refer to the above and to previous correspondence regarding your FOI request, and I can advise that the TGA is continuing to process your request.

As an update, we wish to advise that the decision maker for this matter has decided to not impose charges for the processing of your request and accordingly, a decision is currently being prepared.

Noting our email sent to you on 31 July 2024, as your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents. Therefore, your request was extended by 30 days in accordance with s15(6) of the FOI Act for this to take place.

The current due date for a decision in relation to your request is **13 September 2024**.

Please do not hesitate to contact the FOI team if you have any questions.

Kind regards

s22 [REDACTED]

Freedom of Information

s22 [REDACTED]

Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
T: 02 6289 4630 | E: TGAFOI@health.gov.au
PO Box 100, Woden ACT 2606, Australia
Web: www.tga.gov.au

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From: s22
To: TGA FOI
Subject: Re: FOI 5280 - Notice of Estimate of Charges [SEC=OFFICIAL]
Date: Monday, 29 July 2024 5:59:21 PM
Attachments: IMG_2866.PNG
IMG_2867.PNG

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22,

I believe that the charges should not be applied because it would cause undue hardship to myself. s22

If you require any other details please let me know and thanks for your understanding.

s22
s22

s22



On 29 Jul 2024, at 4:53 pm, TGA FOI <TGAFOI@health.gov.au> wrote:

Dear s22

Please find attached correspondence in relation to your Freedom of Information request.

IMPORTANT: Please include reference to FOI 5280 in your payment.

Consultation

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act, and upon payment of a deposit, the timeframe for processing your request will be extended by 30 days to allow the consultation process to be conducted.

If you have any questions, please do not hesitate to contact the FOI Team.

Kind regards

s22

Freedom of Information

s22

<image001.png>

Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
T: 02 6289 4630 | E: TGAFOI@health.gov.au
PO Box 100, Woden ACT 2606, Australia
Web: www.tga.gov.au

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<FOI 5280 - Estimate of Charges.pdf>

From: [TGA FOI](#)
To: s22
Cc: [TGA FOI](#)
Subject: FOI 5351 - Decision on waiver of charges [SEC=OFFICIAL]
Date: Thursday, 3 October 2024 4:27:39 PM
Attachments: [image001.png](#)
[FOI 5351 - Timeframes following payment SECOFFICIAL.msg](#)

Dear s22

I refer to previous correspondence regarding your FOI request, and I can advise that the TGA is continuing to process your request.

As an update, I write to advise you that the Decision Maker has decided not to impose any charges for the processing of your request.

Accordingly, as you have paid the deposit of \$172.10, the TGA will refund the deposit paid to the original payment method.

Request for extension

As previously advised in our email dated 20 September 2024 (see **attached**), as your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

In accordance with the above, the TGA is currently preparing to consult with the several relevant third parties. As part of the decision-making process, TGA decision-makers carefully consider the submissions made by third parties regarding release of documents, with the aim of making impartial and well-informed decisions that balance the competing interests of applicants and third parties. In this way we hope to negate the need for either applicants or third parties to seek review of our decisions, as this results in further delays to the eventual release of documents. Unfortunately, the time required to thoroughly undertake these processes can occasionally exceed the allotted time available under the FOI Act. With this in mind, the TGA would be very grateful for your consideration of granting a short extension of time under section 15AA of **15 days** for the processing of your request. A decision would subsequently be due on or before **7 November 2024**.

We would greatly appreciate your response by **1pm tomorrow, Friday 4 October 2024**.

Thank you for your patience in this matter and for your further consideration of our request.

Should you have any questions, please don't hesitate to contact the FOI team.

Kind regards

s22

Freedom of Information

s22

Australian Government Department of Health and Aged Care
T: 02 6289 4630 | E: TGAFOI@health.gov.au
PO Box 100, Woden ACT 2606, Australia
Web: www.tga.gov.au

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From: s22
Sent: Friday, September 20, 2024 1:06 PM
To: TGA FOI <TGAFOI@health.gov.au>
Subject: RE: FOI 5351 - Notice of Estimate of Charges [SEC=OFFICIAL]

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Dear s22

Please find attached correspondence in reply.

With kind regards,
s22

From: TGA FOI <TGAFOI@health.gov.au>
Sent: Friday, September 13, 2024 4:15 PM
To: s22
Cc: TGA FOI <TGAFOI@health.gov.au>
Subject: FOI 5351 - Notice of Estimate of Charges [SEC=OFFICIAL]

Dear s22

Please find attached correspondence in relation to your Freedom of Information request.

We note in your email of 19 August 2024, you sought a full waiver of any fees associated with the processing of your FOI request. Pursuant to section 29(1)(f) of the FOI Act, you have 30 days after the issuing of this notice to seek a waiver of charges. If you still intend to seek a full waiver of the charges, please confirm in writing and provide any additional information you wish the TGA to consider in support of your claim.

Consultation

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act, and upon payment of a deposit, the timeframe for processing your request will be extended by 30 days to allow the

consultation process to be conducted.

If you have any questions, please do not hesitate to contact the FOI Team.

Kind regards

s22

Freedom of Information


s22

Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
T: 02 6289 4630 | E: TGAFOI@health.gov.au
PO Box 100, Woden ACT 2606, Australia
Web: www.tga.gov.au

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From: [TGA FOI](#)
To: 
Cc: [TGA FOI](#)
Subject: RE: FOI 5348 - Notice of Estimate of Charges [SEC=OFFICIAL]
Date: Tuesday, 24 September 2024 1:30:56 PM
Attachments: [image001.png](#)

Dear 

I refer to previous correspondence regarding your FOI request 5348.

I write to advise that the decision maker has decided not to impose charges for the processing of your FOI request.

As notified in the Estimate of Charges letter sent to you on 28 August 2024, the processing timeframe was suspended under section 31(2)(a) between the time the charges were issued and receipt of a deposit/decision on the waiver or reduction of fees. Accordingly, as the charges for processing your request are not being imposed, the processing of your request has recommenced.

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act the timeframe for processing your request has been extended by 30 days to allow the consultation process to be conducted.

The current due date for a decision in relation to your request is **12 November 2024**.

If you have any questions or concerns, please don't hesitate to contact the FOI team.

Kind regards



Freedom of Information



Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
T: 02 6289 4630 | E: TGAFOI@health.gov.au
PO Box 100, Woden ACT 2606, Australia
Web: www.tga.gov.au

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-----Original Message-----

From: s22
Sent: Thursday, August 29, 2024 7:01 PM
To: TGA FOI <TGAFOI@health.gov.au>
Subject: Re: FOI 5348 - Notice of Estimate of Charges [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.
Dear Freedom of Information Team,

I wish to contend that the charge has been wrongly assessed. My reasons are as follows.

In Emmanuel Freudenthal and Department of Foreign Affairs and Trade (Freedom of information) [2019] AICmr 15, the Information Commissioner stated at [46]:
“The FOI Guidelines explain that the ‘lowest reasonable cost’ objective should be interpreted broadly in imposing any charges under the FOI Act and that where the cost of calculating and collecting a charge might exceed the cost to the agency to process the request, it would generally be more appropriate not to impose a charge.”

Furthermore, she states:

“In assessing the costs of calculating and collecting a charge, agencies should also take into account the likely costs that may be incurred by the agency, as well as other review bodies, if the applicant decides to seek further review.”

These principles regarding cost assessment are further elaborated upon in subsequent decisions.

The legislative framework for charges and related aspects of the FOI Guidelines is discussed at length in the decision of 'ABX' and Department of Veterans' Affairs (Freedom of information) [2022] AICmr 57 (ABX).

In ABX, the applicant sought IC review of a decision of the Department of Veterans' Affairs (DVA) to impose a charge of \$403.45 to process an FOI request. ABX considers whether a charge should be imposed where the cost to the Commonwealth of assessing, imposing and collecting the charge from the applicant might exceed the cost to DVA of processing the applicant's request (or the amount of the charge itself).

The FOI Commissioner explained at [3]:

“As a general rule, a charge should not be imposed in circumstances where the cost of assessing, imposing and collecting a charge is likely to be greater than the charge itself. In those circumstances, imposing a charge will generally only serve to delay or discourage access while incurring a net cost to the Commonwealth.”

In determining whether a charge should be imposed, the FOI Commissioner stated at [45]:

“Even if a charge could have been correctly imposed by reference to an actual cost of \$291.68, the Department should have considered at the outset whether it was preferable to decide that the applicant was liable to pay a charge at all. The amount of that charge should have raised an obvious question in the minds of those considering its imposition – would it cost the Commonwealth an amount greater than the charge itself to assess and notify the charge, provide the applicant with procedural fairness, and collect the charge? The likely answer to that question would have been ‘yes’. In those circumstances, proceeding with a charge would likely only serve to delay access at a net financial cost to the Commonwealth. While the FOI Act and Charges Regulations would not, by their terms, have prevented the Department from deciding

the applicant was liable to pay a charge, the preferable decision would have been to decide that the applicant was not liable to pay a charge.”

The FOI Commissioner accepted that, in the circumstances of the matter before him, the cost of calculating and collecting a charge might exceed the amount of the charge itself. He noted that the object set out in s 3(4) is not limited to the provision of access at the lowest reasonable cost, but also expresses a parliamentary intention that functions and powers under the FOI Act must be performed and exercised to facilitate and promote the prompt public access to information. The FOI Commissioner was satisfied that having regard to these considerations, and the public resource already applied in relation to the matter, warranted a decision that no charge be applied in the circumstances.

I also wish to bring to your attention recent IC Review decisions regarding whether a charge has been wrongly assessed.

In *Paul Farrell and Services Australia (Freedom of information)* [2023] AICmr 27 (*Paul Farrell and Services Australia*), the Department determined that the applicant is liable to pay a charge of \$342.10 for processing the request. *Services Australia* submitted that ABX was inconsistent with the FOI Guidelines and previous decisions. The Information Commissioner extensively disputed the Department's submissions and addressed the implications of ABX at [35]-[45].

In this IC Review, the applicant had already made a deposit to progress the processing of their FOI request. As the bulk of the cost necessary to administer the charge had already been utilised and spent, this decision under review differs slightly. The Information Commissioner stated at [48]:

“This is notwithstanding that, in my view, a decision not to impose any charge would have been open, and probably would also have been the preferable decision to make, under s 29(4) had *Services Australia* approached the decision-making process differently.”

In *CropLife Australia and Department of Agriculture, Fisheries and Forestry (Freedom of information)* [2024] AICmr 159, the Department determined that the applicant is liable to pay a charge of \$710 for processing the request.

The Assistant Commissioner, Freedom of Information, stated at [25]:

“I also note that in this case, there is a real possibility that the cost of calculating and collecting a charge might exceed the cost to the agency of processing the request, which would militate in favour of the waiver of the charge. As noted in ABX, in such circumstances, proceeding with a charge would likely only serve to delay access at a net financial cost to the Commonwealth.”

Given the extensive case law established by these recent decisions, I strongly urge you to reconsider whether your charge of \$130.28 might incur a net financial cost to the Commonwealth. The Information Commissioner has consistently demonstrated a preference for waiving charges when their collection costs could potentially outweigh the processing costs, particularly in cases where the charges were significantly higher than mine: \$291.68 in ABX, \$342.10 in *Paul Farrell and Services Australia*, and \$710 in *CropLife Australia*. I believe the same logic applies in this instance, and waiving the charge would align with the principles of fairness, efficiency, and promoting prompt public access to information.

Yours sincerely,

-----Original Message-----

Dear s22

Please find attached correspondence in relation to your Freedom of Information request.

IMPORTANT: Please include reference to FOI 5348 in your payment.

The decision maker is yet to make a decision on your request.

Should you wish to proceed with your request, you will note from the attached letter that you are required to pay a deposit before the request can be processed. If you do not pay the deposit within 30 days, your request will be treated as withdrawn.

Consultation

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act, and upon payment of a deposit, the timeframe for processing your request will be extended by 30 days to allow the consultation process to be conducted.

If you have any questions, please do not hesitate to contact the FOI Team.

Kind regards,

Freedom of Information

Therapeutic Goods Administration

Australian Government Department of Health and Aged Care

T: 02 6289 4630 | E: [1][email address]

PO Box 100, Woden ACT 2606, Australia

Web: [2]www.tga.gov.au

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References

Visible links

1. [mailto:\[email address\]](mailto:[email address])
2. <http://www.tga.gov.au/>

Please use this email address for all replies to this request:
foi+request-11916-74d872fd@righttoknow.org.au

This request has been made by an individual using Right to Know. This message and any reply that you make will be published on the internet. More information on how Right to Know works

can be found at:

<https://www.righttoknow.org.au/help/officers>

Please note that in some cases publication of requests and responses will be delayed.

If you find this service useful as an FOI officer, please ask your web manager to link to us from your organisation's FOI page.

From: [TGA FOI](#)
To: s22
Cc: [TGA FOI](#)
Subject: RE: FOI 5343 - Seeking consideration of withdrawal [SEC=OFFICIAL]
Date: Friday, 4 October 2024 5:09:19 PM
Attachments: [image001.png](#)

Dear s22

s22

In addition, the decision maker has decided to waive the charges in full associated with the processing of FOI 5343 and will refund the funds already paid.

I apologise for any confusion caused. Please feel free to contact me if you have any questions about this.

Thank you for your consideration of this matter.

Kind regards

s22

Freedom of Information

s22

Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
T: 02 6289 4630 | E: TGAFOI@health.gov.au
PO Box 100, Woden ACT 2606, Australia
Web: www.tga.gov.au

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s22

From: s22
Sent: Tuesday, September 24, 2024 10:31 AM
To: TGA FOI <TGAFOI@health.gov.au>
Subject: Re: FOI 5343 - Notice of Estimate of Charges [SEC=OFFICIAL]

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Dear s22,

I have paid the full fee.

<image001.png>

I also write to contest charges outlined in the notice provided to me on 20 Sept, proposing that they should not be imposed (FOI Act s 29(1)(f)(ii)).

This FOI relates to a matter of significant public interest. There has been significant interest in this matter in the Federal parliament.

https://www.aph.gov.au/Parliamentary_Business/Hansard/Hansard_Display?

[bid=chamber/hansards/28053/&sid=0133](https://www.aph.gov.au/Parliamentary_Business/Hansard/Hansard_Display?bid=chamber/hansards/28053/&sid=0133)

https://www.aph.gov.au/Parliamentary_Business/Hansard/Hansard_Display?bid=chamber/hansardr/28031/&sid=0025

https://www.aph.gov.au/Parliamentary_Business/Hansard/Hansard_Display?bid=chamber/hansardr/28031/&sid=0185

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https://www.aph.gov.au/Parliamentary_Business/Hansard/Hansard_Display?bid=chamber/hansards/28060/&sid=0164

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https://www.aph.gov.au/Parliamentary_Business/Hansard/Hansard_Display?bid=chamber/hansards/28058/&sid=0091

https://www.aph.gov.au/Parliamentary_Business/Hansard/Hansard_Display?bid=chamber/hansards/28057/&sid=0086

There is more.

There has also been significant media interest in this matter.

<https://theconversation.com/australias-iv-fluids-shortage-will-likely-last-all-year-heres-what-that-means-for-surgeries-237009>

<https://www.abc.net.au/news/2024-07-27/iv-fluids-global-shortage-explainer/104147878>

<https://www.theguardian.com/australia-news/article/2024/aug/16/australia-iv-fluid-shortage-government-distribution>

Documents provided under this FOI will likely be the basis of further journalistic writing. **s22**

- In *Emmanuel Freudenthal and Department of Foreign Affairs and Trade (Freedom of information) [2019] AICmr 15 (29 April 2019)* the Information Commissioner noted the relationship to the FOI in that case and articles

that had been written in relation to it, and questions that had been raised in the parliament (Senate Estimates).

- In *Australian Associated Press Pty Ltd and Department of Immigration and Border Protection [2015] AICmr 65 (2 October 2015)* the Information Commissioner determined “It is likely that the position of the applicant as a media outlet, pursuing investigative journalism, could increase any benefit flowing from the release of the documents in this case.”
- In *MacTiernan and Secretary, Department of Infrastructure and Regional Development (Freedom of information) [2015] AATA 584* the Tribunal stated “When one compares the number of documents identified as within the scope of the FOI request (i.e. 88 documents) and the cost of processing the FOI Request (\$2,291.36) against what the FOI Request relates to (i.e. a proposed \$1 billion (plus) government (taxpayer) funded infrastructure project) the Tribunal considers, on balance, that the giving of access to the documents in question is in the “general public interest” or, at the very least, “in the interest of a substantial section of the public” for the purposes of s 29(5) of the FOI Act and that the charge associated with processing the FOI Request ought be waived under s 29(4) of the FOI Act in the circumstances of this case.

The decision to impose a charge is discretionary. One of the factors that must be considered in the exercise of the discretion is the public interest (s 29(5)(b)).

Noting the circumstances set out above, I ask that the charges be waived.

Kind regards - s22

s22

s22

s22

s22

s22

On 20 Sep 2024, at 8:41 am, TGA FOI <TGAFOI@health.gov.au> wrote:

Dear s22

Please find attached correspondence in relation to your Freedom of Information request.

IMPORTANT: Please include reference to FOI 5343 in your payment.

Consultation

As your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents.

Accordingly, under section 15(6) of the FOI Act, and upon payment of a deposit, the timeframe for processing your request will be extended by 30 days to allow the consultation process to be conducted.

If you have any questions, please do not hesitate to contact the FOI Team.

Kind regards

s22

Freedom of Information

s22

<image001.png>

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 Australian Government Department of Health and Aged Care
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 <FOI 5343 - Estimate of Charges.pdf>

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