



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

s22

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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