



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

TRIM Ref: D19-6109651

Ms Anne Williams

**Email:** [foi+request-5519-23e82380@righttoknow.org.au](mailto:foi+request-5519-23e82380@righttoknow.org.au)

Dear Ms Williams

**FREEDOM OF INFORMATION REQUEST FOI 1324**  
**Estimate of Charges**

I refer to your request dated 12 September 2019 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 seeking documentation that is the actual 'written advice' provided to UCB Australia by the TGA in regards to the aforementioned pre-submission discussions. I am not requesting any other correspondence related to or surrounding that written advice.*

*The 'written advice' refers to part of the correspondence between the TGA and UCB Australia related directly to pre-submission discussions about the drug Xyrem (Sodium Oxybate). These discussions took place in 2018 and written advice was provided by email from TGA to UCB Australia. I refer specifically to the two pre-submission discussions that are described on page 2 of, "Inquiry into Sleep Health Awareness in Australia - Submission 131 - Supplementary Submission 1," which is uploaded at:*

[https://www.aph.gov.au/Parliamentary\\_Bus...](https://www.aph.gov.au/Parliamentary_Bus...)

*"The TGA has been approached in 2018 by potential sponsors for sodium oxybate and has had two pre-submission discussions. Written advice to the sponsors was provided by the TGA at the time and no follow-up applications have been received to date."*

*I understand further that some of the documents relating to these discussions may be published journal articles or studies. If the documents contain information that is published elsewhere I am not seeking it to be reproduced in full, I am only seeking a citation or reference information so that it is identified.*

*I am not seeking access to any personal information of any individual, or duplicate copies in any format. I am not seeking anything that would be considered commercial in-confidence."*

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

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

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

1. Search and retrieval time (including time spent locating relevant files and collating relevant documents contained on those files)	4.5 hours @ \$15.00 per hour	\$67.50
2. Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	8.40 hours @ \$20.00 per hour Less first 5 hours which are free	\$67.98
3. Photocopying of documents	32 pages	\$3.20
4. Postage charges		\$0.00
<b>TOTAL</b>		<b>\$138.68</b>

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 \$138.68, I have decided you are required to pay a deposit of 25 percent, being \$34.67. Details of payment methods are outlined below.

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

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

Please note, should you seek a reduction or waiver of charges on the grounds of financial hardship it would assist the decision maker considering your request if you provide suitable evidence of financial hardship (for example, by providing evidence of receipt of a pension or income support payment; or provide evidence of income, debts or assets). This is consistent with the FOI Guidelines <https://www.oaic.gov.au/freedom-of-information/foi-guidelines/part-4-charges-for-providing-access>. Evidence should be provided at the time of seeking waiver or reduction.

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

### **Timeframes**

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

Once your FOI request has been processed, the TGA will determine the actual charge you must pay before the documents can be provided to you. The final charge for processing your request may be different from the estimate quoted in this letter. If I decide to grant full access to all the documents within the scope of your request, you must pay the actual charges for the time and disbursements involved in processing your request ascertained in

accordance with the table set out above (which may be greater or less than the estimate). However, if you are only granted partial access to the documents you will only be required to pay whichever amount is the lesser of the estimate quoted in this letter and the actual charges.

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

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

### **Payment**

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

- **Credit card payment:**  
Complete the *attached* form (also available via the following link):  
[www.tga.gov.au/form/credit-card-payment-authorisation](http://www.tga.gov.au/form/credit-card-payment-authorisation).
- **Electronic Funds Transfer:**  
Payment can be made in the form of electronic funds transfer to the following account:  
Bank: Commonwealth Bank of Australia  
Account Name: Therapeutic Goods Administration  
BSB: 062909  
Account: 10215498
- **Cheque:**  
Please make cheques payable to Therapeutic Goods Administration, and post to  
FOI Coordinator  
Therapeutic Goods Administration  
PO Box 100  
WODEN ACT 2606

### **Please include reference to FOI 1324 in all forms of payment.**

Details of how to pay and other payment methods can be found at:  
[www.tga.gov.au/about/fees-payments-options.htm](http://www.tga.gov.au/about/fees-payments-options.htm).

**IMPORTANT:** Once payment has been made, please notify the FOI Team via the following email address: [TGA.FOI@tga.gov.au](mailto:TGA.FOI@tga.gov.au).

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

### **Third Party Consultation**

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

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

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

Yours sincerely

A handwritten signature in black ink, appearing to read 'Mark McDonald', written in a cursive style.

Dr Mark McDonald  
Senior Manager  
Prescription Medicines Authorisation Branch  
Therapeutic Goods Administration  
3 October 2019