



Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Ref: D17-485732

Mr Stuart McCarthy
Email: foi+request-3484-655467d4@righttoknow.org.au

Dear Mr McCarthy

FREEDOM OF INFORMATION REQUEST FOI 311-1617
Estimate of Charges

I refer to your request dated 11 May 2017 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

"I hereby request to be provided with a summary of all tafenoquine related AERs submitted to the TGA, to include the information normally available for all drugs via the DAEN.

I also request to be provided with any documents relating to decisions by TGA staff to remove tafenoquine from the publicly accessible DAEN, including but not limited to emails, memos, meeting summaries, file notes and/or correspondence between TGA officials and third parties."

Under the *Freedom of Information (Charges) Regulations 1982* (the Regulations) a charge can be levied in respect of a request for access to documents under the FOI Act. The charge is for 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)	1.25 hours @ \$15.00 per hour	\$18.75
2. Decision making time (including time spent examining the documents, considering exemptions, undertaking consultation, writing the decision and preparing any documents for release)	4.17 hours @ \$20.00 per hour Less first 5 hours which are free	\$0.00
3. Photocopying of documents	5 pages	\$0.50
4. Postage charges		\$0.00
TOTAL		\$19.25

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 \$19.25, I have decided you are required to pay the full amount of \$19.25. Details of payment methods are outlined below.

Under subsection 29(1) of the FOI Act you are required to notify the TGA, in writing, within 30 days of receipt of this notice that you:

- agree to pay the charge (in which case you should also forward the deposit); or
- wish to argue 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
- withdraw your request.

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. Please note that if you are arguing that the charge should be reduced or not imposed because the payment would cause you financial hardship, you believe access would be in the public interest or for any other reason, you must provide sufficient cogent reasons to provide a basis on which the decision maker could reduce, or not impose, the fee.

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 cost of 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 of the amount of the estimate quoted in this letter and actual charge is the **lesser** amount.

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 *Financial Management and Accountability Act 1997*.

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 either of the forms as listed at the attached link
<http://www.tga.gov.au/about/fees-forms-creditcard-authorisation.htm>

- **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 311-1617 in all forms of payment.

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

Please note that it is very important that once payment has been made that the FOI Team is notified via the following email address: TGA.FOI@tga.gov.au. Failure to notify the FOI Team of payment may result in delays to processing times of your FOI request.

Third Party Consultation

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. The TGA is, therefore, required to provide that person, organisation or undertaking 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 is extended by 30 days under subsection 15(6) of the FOI Act where a third party is being consulted. The time period for processing your request will be extended accordingly.

If you require clarification of any of the matters discussed in this letter you should contact Jacki Joester on (02) 6232 8612.

Yours sincerely



Dr Jane Cook
Head
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration

14 June 2017