



Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D19-6251470

Ms Anne Williams

Email: foi+request-5519-23e82380@righttoknow.org.au

Dear Ms Williams

FREEDOM OF INFORMATION REQUEST FOI 1324
Notice of Decision

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..

"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."

Decision Maker

I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Scope of the FOI request

The TGA has identified two (2) documents falling within the scope of your request.

Background

On 12 September 2019 the TGA received a request from you under the FOI Act.

On 24 September 2019 you provided a revised scope (as set out above).

On 3 October 2019 you were advised that the cost of processing your request amounted to \$138.68 and you were asked to pay a deposit of \$34.67. You were also advised at this time of the need to conduct a third party consultation in relation to your request.

On 3 October 2019 the TGA received payment in the amount of \$138.68 for the processing of your request. The third party consultation was subsequently initiated.

Material Considered in Decision-Making

In coming to my decision I had regard to the following:

- the correspondence between the TGA and yourself;
- the documents falling within the scope of the FOI request;
- all relevant papers in the TGA FOI processing file;
- the provisions of the FOI Act in particular section 22;
- the guidelines issued by the Office of the Australian Information Commissioner (OAIC) under section 93A of the FOI Act; and
- consultation with third parties whose documents are involved.

Decision

My decision in relation to the documents falling within the scope of the FOI request is to release two (2) documents in full.

The preliminary estimate of charges associated with processing this FOI request was \$138.68. This amount includes the first five hours of decision making at no cost. In accordance with the *Freedom of Information (Charges) Regulations 2019* (the Charges Regulations) I have calculated the actual charges that can be imposed for processing your request. In this case, the actual charges that can be imposed are \$180.50. While these charges exceed the estimate of charges previously provided to you, the Charges Regulations provides that a higher amount than the estimate can be charged if providing full access to the documents. As my decision is to give you full access to the documents, I have decided to impose the actual charges associated with processing your request.

Therefore, as you have already paid the estimate of \$138.68 in full, you are required to pay the balance of \$41.82 before the documents can be released to you.

Payment

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.
- **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.

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

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

Reasons for Decision

Relevant Documents

There are two (2) documents that have been identified as relevant to your request. A schedule listing the documents identified as falling within the scope of your request is at **Attachment A**. The schedule indicates for each document my decision to release in full.

Under section 22 of the FOI Act, irrelevant information has been redacted from the documents as it is considered to be outside the scope of your request.

The reason for the application of section 22 (irrelevant information) to the documents in issue are set out in detail below. A copy of the relevant provision of the FOI Act is at **Attachment B**.

Subsection 22(1): Documents containing information that is irrelevant to the FOI request

The effect of subsection 22(1) of the FOI Act is that where the granting of access to a document would disclose information that is not within the scope of the request and it is possible to provide a copy with information deleted, the agency can do so unless it is evident that the applicant does not wish to be provided access to such a copy. A copy of subsection 22(1) is at **Attachment B**.

The relevant documents contain information that does not fall within the scope of your FOI request. Specifically, the documents contain personal information such as individual's names which you confirmed you were not seeking as part of your request. Therefore, I consider this information to be outside the scope of your request.

I consider that to provide you with full access to the documents would disclose information that does not fall within the scope of your FOI request. Accordingly, I have decided that the irrelevant information will be deleted under section 22(1) of the FOI Act and a copy of the documents, with the irrelevant information deleted, will be provided to you.

Release of Documents

As a third party whose documents fall within the scope of the request has objected to the release of Documents 1 and 2 in part, I am required, under subsection 27A(6) of the FOI Act, to advise the third party of my decision to release the documents in full and give them an opportunity to seek internal review of my decision or appeal to the OAIC.

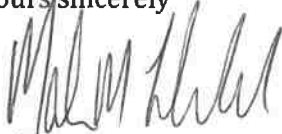
The third party has 30 days in which to seek review or lodge an appeal. Therefore, the documents subject to the 30 day appeal cannot be released to you until this time period has expired, or any internal review or appeal has been completed and my decision to release the document upheld or confirmed.

Review and Complaint Rights

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/

If you have any queries regarding this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely



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

8 November 2019