



Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D17-167107

Stuart McCarthy

Email: foi+request-2897-217ea668@righttoknow.org.au

Dear Mr McCarthy

FREEDOM OF INFORMATION REQUEST FOI 159-1617
Notice of Decision – Request for a waiver of charges

I refer to your request dated 3 January 2017 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

"I hereby request to be provided with any applications, dossiers, submissions or related documents submitted to the TGA by 60 Degrees Pharmaceuticals (60P), 60P sub-contractors including Clinical Network Services (CNS), U.S. Department of Defence officials, Australian Department of Defence officials or other third parties for the purpose of registering tafenoquine for malaria prophylaxis."

Background

On 3 January 2017 the TGA received a request from you under the FOI Act.

On 10 January 2017 you were advised that the costs associated with processing your request amounted to \$1,078.66 and you were asked to:

- agree to pay the charge and forward the deposit; 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.

On 6 February 2017 the TGA received a request for a waiver of further charges on public interest grounds.

Decision Maker

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

I have decided to reduce the charges that can be imposed for the processing of your request by 50%. As the initial estimated charge was \$1,078.66, the revised estimated charge is \$539.33 with an initial deposit of \$134.83.

Material Considered in Decision-Making

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

- your request for documents under the FOI Act dated 3 January 2017;
- my initial decision of 10 January 2017 to impose charges of \$1078.66;

- the correspondence from you of 6 February 2017, requesting that the charges be waived as access to the documents is in the public interest;
- publicly available information about the use of tafenoquine, including by members of the Australian Defence Force;
- 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 Freedom of Information Act 1982 (FOI Guidelines).

Reasons for Decision

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.*

In addition, I must have regard to the matters set out in Chapter 4 of the FOI Guidelines when considering a request not to impose a charge.

As you have not indicated that payment of the charge would cause financial hardship, this is not a relevant consideration in this matter.

Your submission contended that disclosure of the documents would be in the public interest for the following reasons:

- clinical trials of tafenoquine were conducted by public institutions;
- proposals for tafenoquine to be registered by the TGA have been funded by public institutions;
- published research indicates that tafenoquine poses a serious risk to the public in the event that it is registered by the TGA; and
- public scrutiny of the documents prior to registration will assist to mitigate these safety risks.

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 state that it is important to identify the ‘general public interest’ or the ‘substantial section of the public’ that would benefit from disclosure (paragraph 4.81).

Given that tafenoquine is not registered on the Australian Register of Therapeutic Goods (ARTG), use of tafenoquine in Australia has been limited to access under the Special Access Scheme.

In this case, the request for documents is about applications and related documents seeking to register tafenoquine in Australia.

The request is not about the supply of tafenoquine under the TGA’s special access scheme.

Similarly, the request for documents is not about the use of tafenoquine by the Australian Defence Force. Publicly available information on the website of the Department of Defence indicates that tafenoquine was used by ADF troops in 1988/1999 and 2001/2001 in clinical trials.

However, some of the documents identified as within the scope of the request appear to include information about the use of tafenoquine by Australian Defence Force troops in clinical trials. On that basis, I consider that there may be of interest to a substantial section of the public. That is, members of the Australian Defence Force may have an interest in the supply of unapproved therapeutic goods to certain personnel and about any safety issues identified from use of the medicine.

On that basis, I consider that a reduction of 50% on public interest grounds is appropriate.

I am not persuaded that a full waiver of the charges is warranted. Specifically, the request is for applications and related documents seeking to register tafenoquine on the ARTG more generally, and documents relating to their use by the Australian Defence force are only some of the relevant documents. Also, in circumstances where tafenoquine is not registered on the ARTG, I am not persuaded the documents are of sufficient public interest to warrant a full waiver on public interest grounds.

Time limit for processing your FOI request

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 of \$134.83.

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

Can you please include for identification in the subject: FOI 159-1617.

If you have the facilities can you please print and scan the remittance form and send a copy to the following email TGA.FOI@tga.gov.au.

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 and forward the deposit; 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.

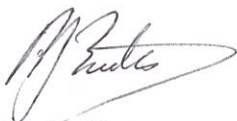
If you fail to notify the TGA within 30 days about what you propose to do, the FOI Act provides under subsection 29(2) that you are taken to have withdrawn your request.

Review and Complaint Rights

If you are not satisfied with this decision, you can either seek internal review or apply to the Office of the Australian Information Commissioner for review of the decision. A statement of review rights is at **Attachment A** to this letter.

If you have any queries regarding this matter, please contact Elizabeth Santolin on (02) 6232 8664.

Yours sincerely



Adrian Bootes
Assistant Secretary, Prescription Medicines Authorisation Branch
Therapeutic Goods Administration

8/2 March 2017



Freedom of information – Your review rights

April 2011

If you disagree with the decision of an Australian Government agency or minister under the *Freedom of Information Act 1982* (the FOI Act), you can ask for the decision to be reviewed. You may want to seek review if you sought certain documents and were not given full access, if someone is to be granted access to information that is about you, if the agency has informed you that it will impose a charge for processing your request or if your application to have your personal information amended was not accepted. There are two ways you can ask for review of a decision: internal review by the agency, and external review by the Australian Information Commissioner.

Internal review

If an agency makes an FOI decision that you disagree with, you can ask the agency to review its decision. The review will be carried out by a different agency officer, usually someone at a more senior level. There is no charge for internal review.

You must apply within 30 days of being notified of the decision, unless the agency extended the application time. You should contact the agency if you wish to seek an extension. The agency must make a review decision within 30 days. If it does not do so, its original decision is considered to be affirmed.

Internal review is not available if a minister or the chief officer of the agency made the decision personally.

Review by the Information Commissioner

The Information Commissioner is an independent office holder who can review the decisions of agencies and ministers under the FOI Act.

Is a review the same as a complaint?

No. The Information Commissioner also investigates complaints about agency actions under the FOI Act. However, if you are complaining that an agency decision is wrong, it will be treated as an application for a review. Your matter will be treated as a complaint when a review would not be practical

or would not address your concerns (for example, if you were not consulted about a document that contains your personal information before it was released). For more information see FOI fact sheet 13 – *Freedom of information: How to make a complaint*.

Do I have to go through the agency's internal review process first?

No. You may apply directly to the Information Commissioner. However, going through the agency's internal review process gives the agency the opportunity to reconsider its initial decision, and your needs may be met more quickly without undergoing an external review process.

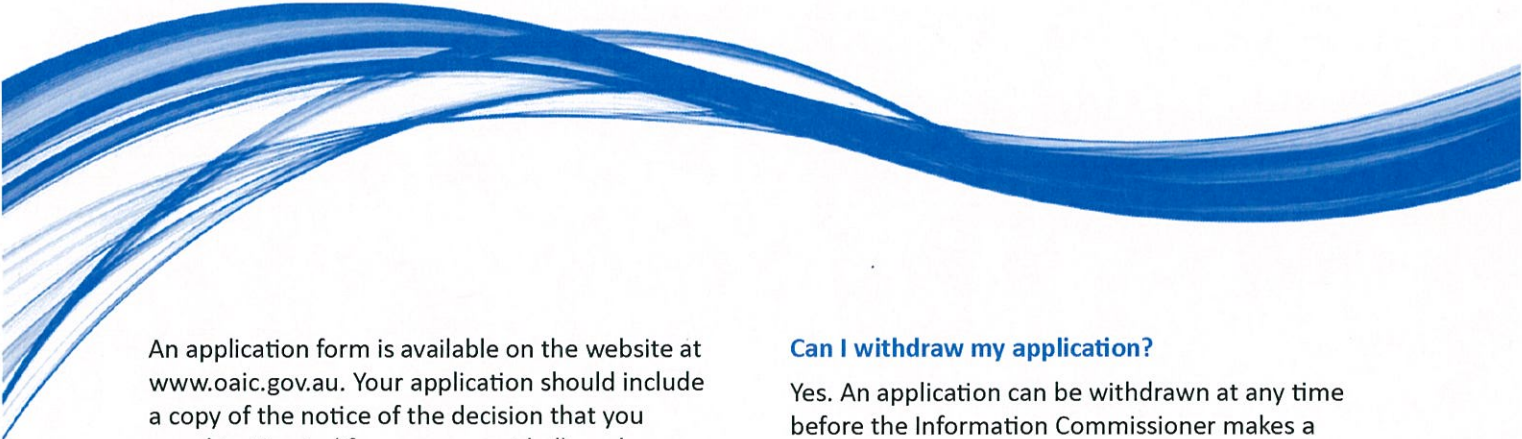
Do I have to pay?

No. The Information Commissioner's review is free.

How do I apply?

You must apply in writing and you can lodge your application in one of the following ways:

online: www.oaic.gov.au
post: GPO Box 2999, Canberra ACT 2601
fax: +61 2 9284 9666
email: enquiries@oaic.gov.au
in person: Level 3,
175 Pitt Street
Sydney NSW 2000



An application form is available on the website at www.oaic.gov.au. Your application should include a copy of the notice of the decision that you are objecting to (if one was provided), and your contact details. You should also set out why you are objecting to the decision.

Can I get help in completing the application?

Yes. The Information Commissioner's staff are available to help you with your application if anything is unclear.

When do I have to apply?

If you are objecting to a decision to refuse access to documents, impose a charge or refuse to amend a document, you must apply to the Information Commissioner within 60 days of being given notice of the decision. If you are objecting to a decision to grant access to another person, you must apply within 30 days of being notified of that decision.

You can ask the Information Commissioner for an extension of time to apply, and this may be granted if the Information Commissioner considers it is reasonable in the circumstances.

Who will conduct the review?

Staff of the Information Commissioner will conduct the review. Only the Information Commissioner, the FOI Commissioner or the Privacy Commissioner can make a decision at the end of the review.

Does the Information Commissioner have to review my matter?

No. The Information Commissioner may decide not to review an application that is frivolous, misconceived or lacking in substance, or if you fail to cooperate with the process or cannot be contacted after reasonable attempts. You cannot appeal against that decision.

Alternatively the Information Commissioner may decide that the Administrative Appeals Tribunal (AAT) would be better placed to review the matter, and if so, will advise you of the procedure for applying to the AAT. This will not be common.

Can I withdraw my application?

Yes. An application can be withdrawn at any time before the Information Commissioner makes a decision.

What happens in the review process?

The review process is designed to be as informal as possible. The Information Commissioner may contact you or any of the other parties to clarify matters and seek more information. The Information Commissioner may also ask the agency or minister to provide reasons for their decision if the reasons given were inadequate.

Most reviews will be made on the basis of the submissions and papers provided by the parties. Sometimes the Information Commissioner may decide to hold a hearing if one of the parties applies. Parties may participate in a hearing by telephone. If confidential matters are raised, the hearing may be held partly or wholly in private.

Will there be other parties to the review?

There may be. The Information Commissioner can join other parties who are affected by the application. For example, if you are objecting to someone else being granted access to information that concerns you, that person may be joined in the review.

Can someone else represent me?

Yes, including a lawyer. However, the Information Commissioner prefers the process to be as informal and cost-effective as possible and does not encourage legal representation.

Will the Information Commissioner look at all documents, including ones that are claimed to be exempt?

Yes. The Information Commissioner's review is a fresh decision, so all the relevant material must be examined, including documents that the agency or minister has declined to release. Developments that have occurred since the original decision may also be considered.



What powers does the Information Commissioner have?

While the review process is designed to be informal, the Information Commissioner has formal powers to require anyone to produce information or documents, to compel anyone to attend to answer questions and to take an oath or affirmation that their answers will be true.

An agency or minister can also be ordered to undertake further searches for documents.

What decisions can the Information Commissioner make?

After reviewing a decision, the Information Commissioner must do one of three things:

- set the decision aside and make a fresh decision
- affirm the decision, or
- vary the decision.

The Information Commissioner will give reasons for the decision.

Will the decision be made public?

Yes. The Information Commissioner will publish decisions on the website. Exempt material (that is, material that is not released) will not be included. Nor will the name of the review applicant, unless that person requests otherwise or there is a special reason to publish it.

What can I do if I disagree with the Information Commissioner's review decision?

You can appeal to the AAT. The Information Commissioner will not be a party to those proceedings. The fee for lodging an AAT application is \$777 (at November 2010), although there are exemptions for health care and pension concession card holders and the AAT can waive the fee on financial hardship grounds.

FOI applications made before 1 November 2010

The Information Commissioner can only review an agency's or minister's FOI decision if you made your FOI request on or after 1 November 2010. If you made your FOI request before 1 November, even if the decision was made after that date, the review process is different.

You must first ask the agency for internal review of the decision. You may then appeal to the AAT if you are not satisfied with the decision.

The information provided in this fact sheet is of a general nature. It is not a substitute for legal advice.

For further information

telephone: 1300 363 992

email: enquiries@oaic.gov.au

write: GPO Box 2999, Canberra ACT 2601
or visit our website at www.oaic.gov.au