



Australian Government
Department of Health
 Therapeutic Goods Administration

TRIM Ref: D17-343100

Dear [REDACTED]

FREEDOM OF INFORMATION REQUEST FOI 280-1617
Notice of Decision

I refer to your request dated 10 April 2017 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:

"List of products approved under Special Access Scheme Category B between Jan 2016 to Dec 2016.

- *Need names of the products Only - example 'Tetracycline 500 mg' (product name and strength approved)*
- *Do not require any more individual details (qty (no of tablets approved for treatment etc, details of prescriber, condition for which approved etc - are not required)..."*

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 three (3) documents falling within the scope of your request.

Background

On 10 April 2017 the TGA received a request from you under the FOI Act.

On 12 April 2017 the TGA requested that you review the scope of your request as it appeared too voluminous. You provided a revised scope on the same day.

On 28 April 2017 you were advised that the cost of processing your request amounted to \$23.98 and you were asked to pay the full amount of \$23.98.

On 29 April 2017 the TGA received the full amount of \$23.98 for the processing of your request.

Material Considered in Decision-Making

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

- the correspondence from you of 10 April 2017 and 12 April 2017 including the terms of your FOI request;

- 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;
- the guidelines issued by the Australian Information Commissioner under section 93A of the *Freedom of Information Act 1982*.

Decision

My decision in relation to the documents falling within the scope of the FOI request is to release three (3) documents in full.

In accordance with the *Freedom of Information (Charges) Regulations 1982* (the Charges Regulations) I have calculated the actual costs associated with processing your request. In this case, the actual costs exceed the estimate of charges (about which you were informed previously). As my decision is to give you access to all the documents within the scope of the request without deletions, regulation 10(3) of the Charges Regulations allows me to charge the actual cost. However, I have decided in the circumstances (only three documents and the difference between the estimate and actual charges being relatively insignificant) not to require you to pay the full amount. The documents can therefore now be released to you.

Reasons for Decision

Relevant Documents

There are three (3) documents that have been identified as relevant to your request. A schedule listing the documents along with the documents themselves is at **Attachment A**.

Release of Documents

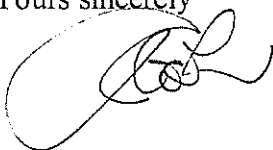
As you have paid the charges in full for the processing of your FOI request, the documents are now being released to you.

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 B** to this letter.

If you have any queries regarding this matter, please contact Jacki Joester on (02) 6232 8612.

Yours sincerely



Jane Cook
Head
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration

May 2017

FOI Request 280-1617 in relation to SAS Category B
The request is for the following:

"List of products approved under Special Access Scheme Category B between Jan 2016 to Dec 2016.

- Need names of the products Only - example 'Tetracycline 500 mg' (product name and strength approved)*
- Do not require any more individual details (qty (no of tablets approved for treatment etc, details of prescriber, condition for which approved etc - are not required)..."*

Schedule of Relevant Documents

Doc. No.	File No.	Folio No.	Author	Addressee	Date	Description	Pages	Decision	Relevant sections of the Act
1		N/A	TGA	N/A	20/4/17	List of medical devices approved between 1.1.16 and 31.12.16	6	Release in full	
2		N/A	TGA	N/A	20/4/17	List of biologicals approved between 1.1.16 and 31.12.16	1	Release in full	
3		N/A	TGA	N/A	20/4/17	List of medicines approved between 1.1.16 and 31.12.16	4	Release in full	





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



FOI Fact Sheet 13

Freedom of information – How to make a complaint

October 2010

You may complain to the Australian Information Commissioner if you have concerns about how an Australian Government agency handled a request for documents under the *Freedom of Information Act 1982* (the FOI Act) or took any other action under that Act. If you are unhappy with the agency's decision about giving or refusing access to documents, you should ask for the decision to be reviewed, which is a separate process.

Disagree with an FOI decision?

If you disagree with an agency's or minister's decision on your request under the FOI Act, you have the right to have the decision reviewed. You can ask an agency to review its decision internally. You also have the right to ask the Information Commissioner to review an agency's or minister's decision. See **FOI Fact Sheet 12 Freedom of information – Your review rights** for more information about the review process.

If you are concerned about the way an agency has handled your matter, you can complain to the Information Commissioner.

What are the powers of the Information Commissioner?

The Information Commissioner can investigate a complaint about how an agency handled an FOI request, or other actions the agency took under the FOI Act. The Information Commissioner cannot investigate a complaint about a minister.

In conducting the investigation the Information Commissioner has the power to:

- make inquiries of an agency
- obtain information from any person
- take possession of, or inspect, any relevant documents.

If the Information Commissioner decides to investigate your complaint, the agency you have complained about will be notified in writing of the complaint. The Information Commissioner conducts investigations of complaints in private.

Who can make a complaint?

Any person can make a complaint about the actions of an agency in relation to an FOI activity. You do not need to have requested documents under the FOI Act.

When should I make a complaint?

You can complain to the Information Commissioner at any time. If your complaint relates to an FOI request you can make the complaint at any stage of the process.

Before making a complaint to the Information Commissioner, you should contact the agency directly to try to resolve your concerns. The Information Commissioner may decide not to investigate your complaint if you have not raised your concerns first with the agency or you have not given the agency a reasonable opportunity to deal with your complaint.



How do I make a complaint?

Your complaint must be in writing and must specify the agency you are complaining about. You can send your complaint to us using the details at the end of this fact sheet. A complaint form is also available on our website at www.oaic.gov.au.

If you need help we can assist you. You can contact us on 1300 363 992 or by email to enquiries@oaic.gov.au.

What information do I need to put in the complaint?

To help the Information Commissioner give the best consideration to your complaint, please provide as much relevant information as possible. Be clear about the issues in your complaint and what action or outcome you would like to see as a result.

Is there a fee for making a complaint?

No. There are no costs involved in making a complaint to the Information Commissioner.

What will happen to my complaint?

An officer of the Information Commissioner will contact you to discuss your complaint and you will be kept informed of the progress of your complaint along the way.

Before deciding whether to investigate your complaint the Information Commissioner may make preliminary inquiries of the agency you have complained about.

If the Information Commissioner decides to investigate your complaint, the Commissioner will write to the agency and request information to assist with the investigation.

Can the Information Commissioner decide not to investigate my complaint?


Yes. The Information Commissioner may decide not to investigate, or may discontinue an investigation, if:

- your complaint does not concern an agency's action under the FOI Act
- it is more appropriate for you to complain to another body (such as the agency or the Commonwealth Ombudsman)
- it is more appropriate for you to ask for the decision to be reviewed
- the agency you complained about has dealt with your complaint, or is in the process of dealing with it
- your complaint is frivolous, lacking in substance or not made in good faith
- you do not have sufficient interest in the matter.

If the Information Commissioner decides not to investigate or discontinues an investigation, the Commissioner will notify you and the agency of the reasons for this in writing.

How will my complaint be resolved?

In some cases the Information Commissioner's investigation and intervention may result in the agency addressing the issues that you have complained about. In other cases the Information Commissioner may make suggestions or recommendations that the agency should implement. You and the agency will be notified in writing of the outcome of the investigation.



If an agency fails to take adequate and appropriate action to implement any recommendations, the Information Commissioner may issue a formal implementation notice. This notice requires the agency to explain what action it will take to implement the recommendations. The Information Commissioner may also provide a written report to the minister responsible for the agency, and the report will be tabled in Parliament.

Your name will not be included in the report unless there is a special reason and you were first consulted.

Investigation by the Ombudsman

The Commonwealth Ombudsman can also investigate complaints about action taken by agencies under the FOI Act. However, if the issue complained about either could be or has been investigated by the Information Commissioner, the Ombudsman will consult the Information Commissioner to avoid the same matter being investigated twice. If the Ombudsman decides not to investigate, the complaint and all relevant documents must be transferred to the Information Commissioner.

The Information Commissioner can also transfer to the Ombudsman a complaint that could more appropriately be investigated by the Ombudsman. This could occur where the FOI complaint is only one part of a wider grievance about an agency's actions. It is unlikely that this will be common. You will be notified in writing if your complaint is transferred.

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

For further information

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