

Australian Government

Department of Health

Therapeutic Goods Administration

Stuart McCarthy

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

Dear Mr McCarthy

FREEDOM OF INFORMATION REQUEST FOI 159-1617

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."

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 eight (8) documents falling within the scope of your request.

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 cost of processing your request amounted to \$1,078.66 and you were asked to pay a deposit of \$269.67. You were also advised at this time of the need to conduct a third party consultation in relation to your request.

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

On 8 March 2017 you were advised that the charges imposed for processing the request have been reduced by 50%, revising the amount to \$539.33 with an initial deposit of \$134.83

On 6 April 2017 the TGA received a deposit in the amount of \$134.83 for the processing of your request. The third party consultation was subsequently initiated on 28 April 2017.

On 25 May 2017 the TGA applied to the Office of the Australian Information Commissioner (OAIC) for an extension of 14 days to process your request. On the same day the OAIC granted the extension.

I note that on 21 April 2017 tafenoquine was granted orphan drug status and this information was published by the TGA on 9 May 2017. I am satisfied that no documents in relation to the granting of orphan drug status were held by the TGA prior to or on the date of your FOI request and therefore no such documents fall within the scope of your request.

Material Considered in Decision-Making

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

• the correspondence from you of 3 January 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, in particular sections 22, 47 and 47F;
- the guidelines issued by the Australian Information Commissioner under section 93A of the *Freedom of Information Act 1982*; and
- consultations with the third parties whose documents are involved.

Decision

Pending applications - Neither confirm nor deny

At the outset, please note that I have decided to neither confirm nor deny the existence of any documents relating to any possible pending application for registration of tafenoquine under subsection 26(2) of the FOI Act (because to do so would cause this letter to be an exempt document under paragraph 47(1)(b) of the FOI Act).

All other documents

My decision in relation to the 8 documents falling within the scope of your request is to:

- release 6 documents in part (Documents 1, 2, 4, 6, 7 and 8); and
- exempt 2 documents in full (Documents 3 and 5).

My decision to exempt information from the documents (either in part or in full) is based on the application of sections 47 and 47F of the FOI Act.

Additionally, irrelevant information has also been redacted from Documents 1, 2, 4, 6, 7 and 8 under section 22 of the FOI Act.

The preliminary estimate of charges associated with processing this FOI request was \$539.33, which includes the first five hours of decision making at no cost and the 50 percent waiver of charges. In accordance with the *Freedom of Information (Charges) Regulations 1982* (the Charges Regulations), I have calculated the actual costs associated with processing your request and decided that the final total amount for processing this FOI request is \$464.35 including the 50 percent waiver. As you have already paid a deposit of \$134.83, you are required to pay the balance owing of \$329.52 before the documents can be released to you.

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 TGAFOI@health.gov.au.

Reasons for Decision

Relevant Documents

There are 8 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 part or exempt in full and where appropriate, the schedule also refers to the provisions that are claimed to apply to each document.

The reasons for the application of these provisions to the documents in issue are set out in detail below. A copy of the relevant provisions 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**.

In an email from the Department of Health to you acknowledging receipt of your FOI request, you were notified that Commonwealth employee names and contact details below Senior Executive Service level would be excluded from the scope unless you advised otherwise. As you did not advise otherwise, I have reducted this information from Documents 1, 2, 4, 6, 7 and 8.

Subsection 26(2): Neither confirm or deny

Under subsection 26(2) of the FOI Act, I am not required to notify you of any matter that would cause this letter to be an exempt document under s.47(1)(b) of the FOI Act. Under s.47(1)(b) of the FOI Act, a document is an exempt document if it contains information of commercial value that would be, or could reasonably be expected to be, destroyed or diminished if it were disclosed. I am satisfied that documents confirming or denying the existence of any pending application for registration of tafenoquine have a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed, for reasons that follow.

Whether a third party business may or may not have submitted a pending application to the TGA for the registration of a medicine is information that has a commercial value to the third party business because it reveals information about the likely timing of entry to the market. If I were to release information about the timing of an application for registration of a medicine (and noting that FOI is considered release to the world at large), this could potentially enable a sponsor of a competing medicine to take steps to maintain its market share at the expense of new market entrant or enable a person to seek to disrupt the process for registration. Therefore I am satisfied that the release of information about pending applications for a medicine (and consequently, about the likely timing of entry to the market) would result in the value of that information being diminished or destroyed.

Were you to be informed of the existence or otherwise of any pending application for registration, you would (whether by this request alone or in combination with later requests of the same kind) be able to determine the timing of any applications made by sponsors. This determination could occur even if exemptions under the FOI Act might reasonably be claimed under paragraph 47(1)(b) by those sponsors.

In the decision of the Secretary, Department of Health and Ageing v iNova Pharmaceuticals (Australia) Pty Ltd [FCA 1442] the Federal Court found that it is open to the TGA, under subsection 26(2) of the FOI Act, in appropriate cases to neither confirm nor deny the existence of documents coming within the scope of the request.

For the above reasons, I am satisfied that it is appropriate in this instance to neither confirm nor deny the existence of any documents relating to any pending application for the registration of tafenoquine.

However, as outlined below, there are some documents that fall within the scope of the request the existence of which I can confirm, because the existence of such documents does not reveal any information about the likely timing of entry to the market for tafenoquine.

Section 47: Trade secrets and commercially valuable information

Under s.47 of the FOI Act, a document is an exempt document if it contains a trade secret (s.47(1)(a)) or contains information that has commercial value that could reasonably be expected to

be destroyed or diminished if it were disclosed (s.47(1)(b)). I consider any information that has a commercial value would also include any information that is a trade secret. Therefore, I have only considered whether the information in question has a commercial value. A copy of s.47(1)(b) is at **Attachment B**.

Paragraph 5.203 of the FOI Guidelines states that the following factors may assist in deciding in a particular case whether information has a commercial value:

- whether the information is known only to the agency or person for whom it has value or, if it is known to others, to what extent that detracts from its intrinsic commercial value
- whether the information confers a competitive advantage on the agency or person to whom it relates for example, it if lowers the cost of production or allows access to markets not available to competitors;
- whether a genuine 'arm's-length' buyer would be prepared to pay to obtain that information;
- whether the information is still current or out of date (out of date information may no longer have any value); and
- whether disclosing the information would reduce the value of a business operation or commercial activity reflected, perhaps, in a lower share price.

Documents 1, 2, 3, 5, 6, 7 and 8 contain technical information regarding tafenoquine supplied by third parties in preparation for a meeting to discuss the product, such as details of clinical trials and other research on the product.

Having regard to the submissions of the third party and taking into account the FOI Guidelines, I am satisfied that some information in Documents 1, 2, 3, 5, 6, 7 and 8 is commercially valuable information, the value of which would be diminished if disclosed. Specifically:

- Information about research conducted on tafenoquine, including the results of that research and the TGA's views in relation to that research, is commercially valuable information to the third party, because the third party has spent a significant amount of time and money on research and on seeking the TGA's views; and
- Release of this information would assist competitors in developing a rival product to tafenoquine. Therefore I am satisfied that a third party would be willing to pay to obtain the information, and that its release would diminish the value of the information to the third parties that have invested in the development of tafenoquine.

Accordingly, I have decided that this information in Documents 1, 2, 3, 5, 6, 7 and 8 (as identified in the schedule at **Attachment A**) is exempt under section 47(1)(b) of the FOI Act and has therefore been deleted.

Subsection 47F(1): Documents containing personal information

A document is conditionally exempt under subsection 47F(1) of the FOI Act if its disclosure under the FOI Act would involve the unreasonable disclosure of personal information about any person (including a deceased person). "Personal information" is defined in the *Privacy Act 1988*, to which the FOI Act links, as "information or an opinion about an identified individual, or an individual who is reasonably identifiable: (a) whether the information or opinion is true or not; and (b) whether the information or opinion is recorded in a material form or not". A copy of subsection 47F(1) is at **Attachment B**.

Documents 1-8 contain names, contact details and other identifying information relating to individuals of relevant third parties (external to the TGA) who were involved in discussions regarding tafenoquine.

I consider the information to be "personal information" as defined in the FOI Act because it is information about individuals, i.e. a name, address (either postal or email) or telephone details, which would allow the individuals to be identified.

At least one individual who has been identified with the development of tafenoquine has received threats. Given this history I am satisfied that it would be unreasonable to disclose this personal information as those individuals may become subject to such threats.

Therefore, I am satisfied that parts of Documents1-8 are conditionally exempt under s.47F(1) because disclosure of those parts of the documents would involve the unreasonable disclosure of personal information. However, I am required under subsection 11A(5) of the FOI Act to give access to the information unless it would, at this time, on balance, be contrary to the public interest.

I consider that the factor favouring giving access to the information at this time is the general public interest in obtaining access to information held by government.

I consider the factors against giving access to the information at this time include the following:

- the information was obtained for a specific purpose and in the expectation that it would be used only for that purpose. It is in the public interest that government only uses information for the purpose(s) for which it has been provided;
- the public interest in protecting the privacy of an individual from unreasonable invasion or harassment in the event that the information is made publicly available; and
- release of the personal information would not add anything to the other information being released.

On balance, I am of the view that giving access to the information at this time would be contrary to the public interest.

For the reasons set out above, I have decided not to disclose the personal information in Documents 1-8 (as identified in the schedule at **Attachment A**). The exempt information in Documents 1-8 has been deleted.

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 C** to this letter.

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

Yours sincerely

Adrian Bootes

Assistant Secretary

Prescription Medicines Authorisation Branch

Therapeutic Goods Administration

// June 2017

FOI 159-1617

FOI Request 159-1617 in relation to Tafenoquine The request is for the following:

"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 Defense officials, Australian Department of Defence officials or other third parties for the purpose of registering tafenoquine for malaria prophylaxis."

Schedule of Relevant Documents

Doc. No.	File No.	Author	Addressee	Date	Description	Pages	Decision	Relevant sections of the FOI Act
 i	R13/234390	TGA	TGA	15/02/2013	Email re request for scientific advice meeting	10	Release in part	s 22 s 47F s 47
2	R13/283562	TGA	Third Party	22/03/2013	Email regarding meeting	1	Release in part	s 22 s 47F s 47
en en	R13/315243	Third Party	TGA	22/04/2013	PowerPoint presentation slides	9	Exempt in full	s 47F s 47
4	R13/366672	Third Party	TGA	03/05/2013	Letter advising of conflict of interest.	3	Release in part	s 22 s 47F
רט	R13/315244	Third Party	TGA	January 2013	Briefing document for TGA Scientific Advice Meeting	303	Exempt in full	s 47F s 47
9	R13/391272	Third Party	TGA	17/05/2013	Email re Draft minutes	5	Release in part	s 22 s 47F s 47
7	R13/391668	TGA	Third party	17/05/2013	Email re Draft minutes	2	Release in part	s 22 s 47F s 47
∞	R13/423333	Third Party	TGA	30/05/2013	Email re minutes and meeting	73	Release in part	s 22 s 47F s 47



Freedom of Information Act 1982

11A Access to documents on request

(5) The agency or Minister must give the person access to the document if it is conditionally exempt at a particular time unless (in the circumstances) access to the document at that time would, on balance, be contrary to the public interest.

Note 1: Division 3 of Part IV provides for when a document is conditionally exempt.

Note 2: A conditionally exempt document is an exempt document if access to the document would, on balance, be contrary to the public interest (see section 31B (exempt documents for the purposes of Part IV)).

Note 3: Section 11B deals with when it is contrary to the public interest to give a person access to the document.

22 Deletion of exempt matter or irrelevant material

- (1) Where:
 - (a) an agency or Minister decides:
 - (i) not to grant a request for access to a document on the ground that it is an exempt document; or
 - (ii) that to grant a request for access to a document would disclose information that would reasonably be regarded as irrelevant to that request; and
 - (b) it is possible for the agency or Minister to make a copy of the document with such deletions that the copy:
 - (i) would not be an exempt document; and
 - (ii) would not disclose such information; and
 - (c) it is reasonably practicable for the agency or Minister, having regard to the nature and extent of the work involved in deciding on and making those deletions and the resources available for that work, to make such a copy;

the agency or Minister shall, unless it is apparent from the request or as a result of consultation by the agency or Minister with the applicant, that the applicant would not wish to have access to such a copy, make, and grant access to, such a copy.

- (2) Where access is granted to a copy of a document in accordance with subsection (1):
 - (a) the applicant must be informed:
 - (i) that it is such a copy; and
 - (ii) of the ground for the deletions; and
 - (iii) if any matter deleted is exempt matter because of a provision of this Act—that the matter deleted is exempt matter because of that provision; and
 - (b) section 26 does not apply to the decision that the applicant is not entitled to access to the whole of the document unless the applicant requests the agency or Minister to furnish to him or her a notice in writing in accordance with that section.

27 Consultation—business documents

Scope

- (1) This section applies if:
 - (a) a request is made to an agency or Minister for access to a document containing information (*business information*) covered by subsection (2) in respect of a person, organisation or undertaking; and
 - (b) it appears to the agency or Minister that the person, organisation or proprietor of the undertaking (the *person or organisation concerned*) might reasonably wish to make a contention (the *exemption contention*) that:
 - (i) the document is exempt under section 47 (trade secrets etc.); or
 - (ii) the document is conditionally exempt under section 47G (business information) and access to the document would, on balance, be contrary to the public interest for the purposes of subsection 11A(5).

Note: Access must generally be given to a conditionally exempt document unless it would be contrary to the public interest (see section 11A).

- (2) This subsection covers the following information:
 - (a) in relation to a person—information about the person's business or professional affairs;
 - (b) in relation to an organisation or undertaking—information about the business, commercial or financial affairs of the organisation or undertaking.
- (3) In determining, for the purposes of paragraph (1)(b), whether the person or organisation concerned might reasonably wish to make an exemption contention because of business information in a document, the agency or Minister must have regard to the following matters:
 - (a) the extent to which the information is well known;
 - (b) whether the person, organisation or undertaking is known to be associated with the matters dealt with in the information;
 - (c) the availability of the information from publicly accessible sources:
 - (d) any other matters that the agency or Minister considers relevant.

Opportunity to make submissions

- (4) The agency or Minister must not decide to give access to the document unless:
 - (a) the person or organisation concerned is given a reasonable opportunity to make submissions in support of the exemption contention; and
 - (b) the agency or the Minister has regard to any submissions so made.
- (5) However, subsection (4) only applies if it is reasonably practicable for the agency or Minister to give the person or organisation concerned a reasonable opportunity to make submissions in support of the exemption contention, having regard to all the circumstances (including the application of subsections 15(5) and (6) (time limits for processing requests)).

Notice of decision to give access

- (6) If the agency or Minister decides to give access to the document, the agency or Minister must give written notice of the decision to both of the following:
 - (a) the person or organisation concerned;
 - (b) the applicant.

Access not to be given until review or appeal opportunities have run out

- (7) However, the agency or Minister must not give the applicant access to the document unless, after all the opportunities of the person or organisation concerned for review or appeal in relation to the decision to give access to the document have run out, the decision to give access still stands, or is confirmed.
 - Note 1: The decision to give access to the document is subject to internal review (see Part VI), review by the Information Commissioner (see Part VII) and review by the Tribunal (see Part VIIA).
 - Note 2: For when all opportunities for review or appeal in relation to the decision to give access to the document have *run out*, see subsection 4(1).

Notice and stay of decision not to apply unless submission made in support of exemption contention

(8) Subsections (6) and (7) do not apply unless the person or organisation concerned makes a submission in support of the exemption contention as allowed under paragraph (4)(a).

Edited copies and business information

- (9) This section applies:
 - (a) in relation to an edited copy of a document—in the same way as it applies to the document; and
 - (b) in relation to a document containing business information—to the extent to which the document contains such information.

27A Consultation—documents affecting personal privacy

Scope

- (1) This section applies if:
 - (a) a request is made to an agency or Minister for access to a document containing personal information about a person (including a person who has died); and
 - (b) it appears to the agency or Minister that the person or the person's legal personal representative (the *person concerned*) might reasonably wish to make a contention (the *exemption contention*) that:
 - (i) the document is conditionally exempt under section 47F; and
 - (ii) access to the document would, on balance, be contrary to the public interest for the purposes of subsection 11A(5).

Note: Access must generally be given to a conditionally exempt document unless it would be contrary to the public interest (see section 11A).

- (2) In determining, for the purposes of paragraph (1)(b), whether the person concerned might reasonably wish to make an exemption contention because of personal information in a document, the agency or Minister must have regard to the following matters:
 - (a) the extent to which the information is well known:
 - (b) whether the person to whom the information relates is known to be (or to have been) associated with the matters dealt with in the information;
 - (c) the availability of the information from publicly accessible sources;
 - (d) any other matters that the agency or Minister considers relevant.

Opportunity to make submissions

(3) The agency or Minister must not decide to give the applicant access to the document unless:

- (a) the person concerned is given a reasonable opportunity to make submissions in support of the exemption contention; and
- (b) the agency or the Minister has regard to any submissions so made.
- (4) However, subsection (3) only applies if it is reasonably practicable for the agency or Minister to give the person concerned a reasonable opportunity to make submissions in support of the exemption contention, having regard to all the circumstances (including the application of subsections 15(5) and (6) (time limits for processing requests)).

Decision to give access

- (5) If the agency or Minister decides to give access to the document, the agency or Minister must give written notice of the decision to both of the following:
 - (a) the person concerned;
 - (b) the applicant.

Access not to be given until review or appeal opportunities have run out

- (6) However, the agency or Minister must not give the applicant access to the document unless, after all the opportunities of the person concerned for review or appeal in relation to the decision to give access to the document have run out, the decision to give access still stands, or is confirmed.
 - Note 1: The decision to give access to the document is subject to internal review (see Part VI), review by the Information Commissioner (see Part VII) and review by the Tribunal (see Part VIIA).
 - Note 2: For when all opportunities for review or appeal in relation to the decision to give access to the document have *run out*, see subsection 4(1).

Notice and stay of decision not to apply unless submission made in support of exemption contention

(7) Subsections (5) and (6) do not apply unless the person concerned makes a submission in support of the exemption contention as allowed under paragraph (3)(a).

Edited copies and personal information

- (8) This section applies:
 - (a) in relation to an edited copy of a document—in the same way as it applies to the document; and
 - (b) in relation to a document containing personal information—to the extent to which the document contains such information.

33 Documents affecting national security, defence or international relations

A document is an exempt document if disclosure of the document under this Act:

- (a) would, or could reasonably be expected to, cause damage to:
 - (i) the security of the Commonwealth;
 - (ii) the defence of the Commonwealth; or
 - (iii) the international relations of the Commonwealth; or
- (b) would divulge any information or matter communicated in confidence by or on behalf of a foreign government, an authority of a foreign government or an international organization to the Government of the Commonwealth, to an authority of the Commonwealth or to a person receiving the communication on behalf of the Commonwealth or of an authority of the Commonwealth.

37 Documents affecting enforcement of law and protection of public safety

- (1) A document is an exempt document if its disclosure under this Act would, or could reasonably be expected to:
 - (a) prejudice the conduct of an investigation of a breach, or possible breach, of the law, or a failure, or possible failure, to comply with a law relating to taxation or prejudice the enforcement or proper administration of the law in a particular instance;
 - (b) disclose, or enable a person to ascertain, the existence or identity of a confidential source of information, or the non-existence of a confidential source of information, in relation to the enforcement or administration of the law; or
 - (c) endanger the life or physical safety of any person.
- (2) A document is an exempt document if its disclosure under this Act would, or could reasonably be expected to:
 - (a) prejudice the fair trial of a person or the impartial adjudication of a particular case;
 - (b) disclose lawful methods or procedures for preventing, detecting, investigating, or dealing with matters arising out of, breaches or evasions of the law the disclosure of which would, or would be reasonably likely to, prejudice the effectiveness of those methods or procedures; or
 - (c) prejudice the maintenance or enforcement of lawful methods for the protection of public safety.
- (2A) For the purposes of paragraph (1)(b), a person is taken to be a confidential source of information in relation to the enforcement or administration of the law if the person is receiving, or has received, protection under a program conducted under the auspices of the Australian Federal Police, or the police force of a State or Territory, for the protection of:
 - (a) witnesses; or
 - (b) people who, because of their relationship to, or association with, a witness need, or may need, such protection; or
 - (c) any other people who, for any other reason, need or may need, such protection.
 - (3) In this section, law means law of the Commonwealth or of a State or Territory.

45 Documents containing material obtained in confidence

- (1) A document is an exempt document if its disclosure under this Act would found an action, by a person (other than an agency, the Commonwealth or Norfolk Island), for breach of confidence.
- (2) Subsection (1) does not apply to a document to which subsection 47C(1) (deliberative processes) applies (or would apply, but for subsection 47C(2) or (3)), that is prepared by a Minister, a member of the staff of a Minister, or an officer or employee of an agency, in the course of his or her duties, or by a prescribed authority or Norfolk Island authority in the performance of its functions, for purposes relating to the affairs of an agency or a Department of State unless the disclosure of the document would constitute a breach of confidence owed to a person or body other than:
 - (a) a person in the capacity of Minister, member of the staff of a Minister or officer of an agency; or
 - (b) an agency, the Commonwealth or Norfolk Island.

47 Documents disclosing trade secrets or commercially valuable information

- (1) A document is an exempt document if its disclosure under this Act would disclose:
 - (a) trade secrets; or
 - (b) any other information having a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.
- (2) Subsection (1) does not have effect in relation to a request by a person for access to a document:
 - (a) by reason only of the inclusion in the document of information concerning that person in respect of his or her business or professional affairs; or
 - (b) by reason only of the inclusion in the document of information concerning the business, commercial or financial affairs of an undertaking where the person making the request is the proprietor of the undertaking or a person acting on behalf of the proprietor; or
 - (c) by reason only of the inclusion in the document of information concerning the business, commercial or financial affairs of an organisation where the person making the request is the organisation or a person acting on behalf of the organisation.
- (3) A reference in this section to an undertaking includes a reference to an undertaking that is carried on by, or by an authority of, the Commonwealth, Norfolk Island or a State or by a local government authority.

47E Public interest conditional exemptions—certain operations of agencies

A document is conditionally exempt if its disclosure under this Act would, or could reasonably be expected to, do any of the following:

- (a) prejudice the effectiveness of procedures or methods for the conduct of tests, examinations or audits by an agency:
- (b) prejudice the attainment of the objects of particular tests, examinations or audits conducted or to be conducted by an agency;
- (c) have a substantial adverse effect on the management or assessment of personnel by the Commonwealth, by Norfolk Island or by an agency;
- (d) have a substantial adverse effect on the proper and efficient conduct of the operations of an agency.

Note: Access must generally be given to a conditionally exempt document unless it would be contrary to the public interest (see section 11A).

47F Public interest conditional exemptions—personal privacy

General rule

- (1) A document is conditionally exempt if its disclosure under this Act would involve the unreasonable disclosure of personal information about any person (including a deceased person).
- (2) In determining whether the disclosure of the document would involve the unreasonable disclosure of personal information, an agency or Minister must have regard to the following matters:
 - (a) the extent to which the information is well known;

- (b) whether the person to whom the information relates is known to be (or to have been) associated with the matters dealt with in the document;
- (c) the availability of the information from publicly accessible sources;
- (d) any other matters that the agency or Minister considers relevant.
- (3) Subject to subsection (5), subsection (1) does not have effect in relation to a request by a person for access to a document by reason only of the inclusion in the document of matter relating to that person.

Access given to qualified person instead

- (4) Subsection (5) applies if:
 - (a) a request is made to an agency or Minister for access to a document of the agency, or an official document of the Minister, that contains information concerning the applicant, being information that was provided by a qualified person acting in his or her capacity as a qualified person; and
 - (b) it appears to the principal officer of the agency or to the Minister (as the case may be) that the disclosure of the information to the applicant might be detrimental to the applicant's physical or mental health, or well-being.
- (5) The principal officer or Minister may, if access to the document would otherwise be given to the applicant, direct that access to the document, so far as it contains that information, is not to be given to the applicant but is to be given instead to a qualified person who:
 - (a) carries on the same occupation, of a kind mentioned in the definition of *qualified* person in subsection (7), as the first-mentioned qualified person; and
 - (b) is to be nominated by the applicant.
- (6) The powers and functions of the principal officer of an agency under this section may be exercised by an officer of the agency acting within his or her scope of authority in accordance with arrangements referred to in section 23.
- (7) In this section:

qualified person means a person who carries on, and is entitled to carry on, an occupation that involves the provision of care for the physical or mental health of people or for their well-being, and, without limiting the generality of the foregoing, includes any of the following:

- (a) a medical practitioner;
- (b) a psychiatrist;
- (c) a psychologist;
- (d) a counsellor:
- (e) a social worker.

Note: Access must generally be given to a conditionally exempt document unless it would be contrary to the public interest (see section 11A).

47G Public interest conditional exemptions—business

- (1) A document is conditionally exempt if its disclosure under this Act would disclose information concerning a person in respect of his or her business or professional affairs or concerning the business, commercial or financial affairs of an organisation or undertaking, in a case in which the disclosure of the information:
 - (a) would, or could reasonably be expected to, unreasonably affect that person adversely in respect of his or her lawful business or professional affairs or that

- organisation or undertaking in respect of its lawful business, commercial or financial affairs; or
- (b) could reasonably be expected to prejudice the future supply of information to the Commonwealth, Norfolk Island or an agency for the purpose of the administration of a law of the Commonwealth or of a Territory or the administration of matters administered by an agency.
- (2) Subsection (1) does not apply to trade secrets or other information to which section 47 applies.
- (3) Subsection (1) does not have effect in relation to a request by a person for access to a document:
 - (a) by reason only of the inclusion in the document of information concerning that person in respect of his or her business or professional affairs; or
 - (b) by reason only of the inclusion in the document of information concerning the business, commercial or financial affairs of an undertaking where the person making the request is the proprietor of the undertaking or a person acting on behalf of the proprietor; or
 - (c) by reason only of the inclusion in the document of information concerning the business, commercial or financial affairs of an organisation where the person making the request is the organisation or a person acting on behalf of the organisation.
- (4) A reference in this section to an undertaking includes a reference to an undertaking that is carried on by, or by an authority of, the Commonwealth, Norfolk Island or a State or by a local government authority.
- (5) For the purposes of subsection (1), information is not taken to concern a person in respect of the person's professional affairs merely because it is information concerning the person's status as a member of a profession.

Note: Access must generally be given to a conditionally exempt document unless it would be contrary to the public interest (see section 11A).

FOI fact sheet 12

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 agency fails to take adequate and appropriate action to implement any recommendations, the Information Commissioner may issue а 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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