



Australian Government
Department of Health and Aged Care

Reference: FOI 4150

Mr Rex Banner
By Email: foi+request-9691-b71be27c@righttoknow.org.au

Dear Mr Banner,

Decision on your Freedom of Information Request

I refer to your request of 12 December 2022, to the Department of Health and Aged Care (the department), seeking access under the *Freedom of Information Act 1982* (Cth) (FOI Act) to:

I am writing to request access to the evidence of efficacy of Escitalopram, as required for listing on the Pharmaceutical Benefits Scheme (PBS).

Please provide all relevant information, including any studies, clinical trials, or other evidence that has been used to evaluate the efficacy of Escitalopram for inclusion on the PBS.

I am authorised under subsection 23(1) of the FOI Act to make decisions in relation to Freedom of Information requests. I am writing to notify you of my decision on your request.

FOI decision

I have identified 24 documents that are relevant to your request. These documents were in the possession of the department when your request was received.

I have decided to:

- give access to 10 documents in full, and
- give access to 14 documents in part, subject to the deletion of irrelevant or exempt material.

A schedule setting out the documents relevant to your request, with my decision in relation to those documents, is at **ATTACHMENT A**.

My reasons for not providing access to material that has been deleted from the documents are set out in **ATTACHMENT B**.

Legislative provisions

The FOI Act, including the provisions referred to in my decision, are available on the Federal Register of Legislation website: www.legislation.gov.au/Series/C2004A02562.

Your review rights

I have set out your review rights at **ATTACHMENT C**.

Publication

Where I have decided to release documents to you, the department may also publish the released material on its Disclosure Log. The department will not publish personal or business affairs information where it would be unreasonable to do so.

For your reference the department's Disclosure Log can be found at:
www.health.gov.au/resources/foi-disclosure-log.

Contacts

If you require clarification of any matters discussed in this letter you can contact the FOI Section on (02) 6289 1666 or at FOI@health.gov.au.

Yours sincerely



Natasha Ploenges
Assistant Secretary
Office of Health Technology Assessment

6 March 2023

ATTACHMENT A.

**SCHEDULE OF DOCUMENTS
FOI 4150**

Doc	Pages	Date	Description	Decision on access ¹	Relevant provision/s of FOI Act
1	314 (3 pages released)	25/09/2009	March 2007 Ratified Consolidated Minutes	RI	22
2	389 (8 Pages Released)	31/07/2009	March 2008 Ratified consolidated minutes	REI	22, 38
3	183 (4 pages released)	17/09/2008	September 2003 ratified consolidated minutes	RI	22
4	96 (48 pages released)	08/05/2018	September 2003 main submission body in relation to document 3.	RI	22
5	60 (27 pages released)	30/10/2006	March 2007 main submission body in relation to document 1	RI	22
6	178 (159 pages released)	28/10/2007	March 2008 main submission body - Clinical Evaluation For The Main Indication in relation to document 2	REI	22, 38, 47E(d)
7	113 (88 Pages released)	28/10/2007	March 2008 main submission body - Clinical Evaluation For The Main Indication in relation to document 2	REI	22, 38, 47E(d)
8	28	29/09/2007	Attachment 1 to main submission body document 6 and 7. Australian Product Information for Lexapro	R	

¹ R = Release in full, RE = Release with exempt information deleted, RI = Release with irrelevant information deleted, RE I= Release with exempt and irrelevant information deleted

9	42	24/10/2007	Attachment 2 to main submission body document 6. "Epidemiology of generalised anxiety disorder (GAD)"	R	
10	137	24/10/2007	Attachment 4 to main submission body document 6. "Details of the Literature Searches Conducted for Escitalopram GAD Submission"	REI	22, 38, 47E(d)
11	8	24/10/2007	Attachment 5 to main submission body document 6. "Detailed assessment of the measures taken by investigators to minimise bias in the randomised trials (addendum to Section B.3)"	R	
12	51	24/10/2007	Attachment 6 to main submission body document 6. "Meta-Analysis Strategy and Results for GAD"	RE	38
13	35	28/10/2007	Attachment 7 to main submission body document 6. "Secondary outcome results for the individual studies (Section B.6.3 of the submission)"	R	
14	35	24/10/2007	Attachment 9 to main submission body document 6. "Additional Statistical Analyses"	R	
15	32	24/10/2007	Attachment 10 to main submission body document 6. "GAD and co-morbidities clinical evidence"	R	
16	42	24/10/2007	Attachment 2 to main submission body document 7. "Epidemiology of social anxiety disorder (SAD) or social phobia"	R	

17	53	24/10/2007	Attachment 4 to main submission body document 7. "Details of the literature searches conducted"	RE	38, 47E(d)
18	33	24/10/2007	Attachment 5 to main submission body document 7. "Meta-Analysis Strategy and Results for SAD"	R	47E(d)
19	17	24/10/2007	Attachment 6 to main submission body document 7. "Secondary outcome results for the individual studies (section B.6.4 of the submission)"	R	
20	16	28/10/2007	Attachment 8 to main submission body document 7. "SAD and co-morbidities clinical evidence"	R	
21	73	12/01/2023	Appendix 4 "Study 9903" for document 4	RI	22
22	76	12/01/2023	Appendix 5 "Study 99022" for document 4.	RI	22
23	13 (8 Pages released)	12/01/2023	Appendix 7 "Escitalopram Flexible Dose Study" for document 4	RI	22
24	35	12/01/2023	Appendix 8 "Clinical Expert Report" for document 4.	RI	22

ATTACHMENT B.

**REASONS FOR DECISION
FOI 4150**

1. Material taken into account

In making my decision, I had regard to the following:

- the FOI Act
- guidelines issued by the Australian Information Commissioner under section 93A of the FOI Act (FOI Guidelines)
- the terms of your FOI request as outlined above
- submissions from third parties consulted about documents which contain information concerning them
- the content of the documents sought, and
- advice from departmental officers with responsibility for matters relating to the documents sought.

2. Finding of facts and reasons for decision

My findings of fact and reasons for deciding that the exemptions identified in the schedule of documents apply to the parts of documents are set out below.

3. Section 38 - Documents to which secrecy provisions of enactments apply

Section 38 of the FOI Act provides that a document is an exempt document if disclosure of the document, or information contained in the document, is prohibited under a provision of an enactment; and that provision is specified in Schedule 3 of the FOI Act.

Relevantly, Schedule 3 of the FOI Act specifies the following secrecy provision the [*National Health Act 1953*](#), subsections 135A(1), (4) and (9).

I am satisfied that the information contained in the parts of the documents marked 's38' are subject to the secrecy provisions contained in the *National Health Act 1953*, subsections 135A(1), (4) and (9).

I am further satisfied that subsections 38(1A) and 38(2) of the FOI Act do not apply in this instance are not relevant to my decision.

For the reasons outlined above, I have decided that the parts of the documents marked 's38' are exempt from disclosure under section 38 of the FOI Act.

4. Section 47E - Documents affecting certain operations of agencies

Section 47E of the FOI Act provides that a document is conditionally exempt if its disclosure 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 or by an agency;
- (d) have a substantial adverse effect on the proper and efficient conduct of the operations of an agency.

Paragraph 6.120 of the FOI Guidelines states:

An agency's operations may not be substantially adversely affected if the disclosure would, or could reasonably be expected to lead to a change in the agency's processes that would enable those processes to be more efficient. For example, in *Re Scholes and Australian Federal Police* [1996] AATA 347, the AAT found that the disclosure of particular documents could enhance the efficiency of the Australian Federal Police as it could lead to an improvement of its investigation process.

Paragraph 6.123 of the FOI Guidelines states that the predicted effect must bear on the department's 'proper and efficient' operations, that is, the department is undertaking its expected activities in an expected manner. Where disclosure of the documents reveals unlawful activities or inefficiencies, this element of the conditional exemption will not be met and the conditional exemption will not apply.

I am satisfied that the parts of the documents marked 's47E(d)' contains information which, if disclosed, would or could reasonably be expected to, have a substantial and an unreasonable effect on the department's proper and efficient operations. These are operational activities that are being undertaken in an expected and lawful manner, and would not reveal inefficiencies in the way in which the department conducts those operational activities.

For the reasons outlined above, I have decided that the parts of the documents marked 's47E' are conditionally exempt from disclosure under section 47E of the FOI Act.

Where a document is found to be conditionally exempt, the department must give access to that document unless access to the document at this time would, on balance, be contrary to the public interest. I have addressed the public interest considerations below.

5. Disclosure is not in the public interest

Pursuant to subsection 11A(5) of the FOI Act, the department must give access to conditionally exempt documents unless access to the documents at that time would,

on balance, be contrary to the public interest. I have therefore considered whether disclosure of the document/s would be contrary to the public interest.

Paragraph 6.5 of the FOI Guidelines states:

The public interest test is considered to be:

- something that is of serious concern or benefit to the public, not merely of individual interest
- not something of interest to the public, but in the interest of the public
- not a static concept, where it lies in a particular matter will often depend on a balancing of interests
- necessarily broad and non-specific and
- relates to matters of common concern or relevance to all members of the public, or a substantial section of the public.

Factors favouring disclosure

Section 11B of the FOI Act provides that factors favouring access to documents in the public interest include whether access to the documents would do any of the following:

- promote the objects of the FOI Act (including all matters set out in sections 3 and 3A)
- inform debate on a matter of public importance
- promote effective oversight of public expenditure, or
- allow a person to access his or her own personal information.

Having regard to the above, I consider that disclosure of the conditionally exempt information at this time:

- would provide access to documents held by an agency of the Commonwealth which would promote the objects of the FOI Act by providing the Australian community with access to information held by the Australian Government.
- would not inform debate on a matter of public importance

Factors weighing against disclosure

I consider that the following public interest factors weigh against disclosure of the conditionally exempt information at this time, on the basis that disclosure:

s47E(d)

- could reasonably have a substantial adverse effect on the proper and efficient conduct of the operations of an agency.

In making my decision, I have not taken into account any of the irrelevant factors set out in subsection 11B(4) of the FOI Act, which are:

- (a) access to the document could result in embarrassment to the Commonwealth Government, or cause a loss of confidence in the Commonwealth Government;
- (b) access to the document could result in any person misinterpreting or misunderstanding the document;
- (c) the author of the document was (or is) of high seniority in the agency to which the request for access to the document was made;
- (d) access to the document could result in confusion or unnecessary debate.

Conclusion

For the reasons set out above, after weighing all public interest factors for and against disclosure, I have decided that, on balance, disclosure of the conditionally exempt information would be contrary to the public interest. I am satisfied that the benefit to the public resulting from disclosure is outweighed by the benefit to the public of withholding the information.

6. Section 22 – deletion of irrelevant material

Section 22 of the FOI Act applies to documents containing exempt material (subparagraph (1)(a)(i)) and irrelevant information (subparagraph (1)(a)(ii)) and allows an agency to delete such material from a document.

I have deleted material in the documents which can reasonably be regarded as irrelevant to your request and prepared an edited copy for release. This information has been marked 's22' in the documents released to you.

ATTACHMENT C.

YOUR REVIEW RIGHTS

If you are dissatisfied with my decision, you may apply for a review.

Internal review

You can request internal review within 30 days of you receiving this decision. An internal review will be conducted by a different officer from the original decision-maker.

No particular form is required to apply for review although it will assist your case to set out the grounds on which you believe that the original decision should be changed.

Applications for internal review can be made by:

Email: FOI@health.gov.au

Mail: FOI Unit (MDP 516)
Department of Health
GPO Box 9848
CANBERRA ACT 2601

If you choose to seek an internal review, you will also have a right to apply for Information Commissioner review (IC review) of the internal review decision once it has been provided to you.

Information Commissioner (IC) review or complaint

You also have the right to seek IC review of this decision. For FOI applicants, an application for IC review must be made in writing within 60 days of the decision. For third parties who object to disclosure of their information, an application for IC review must be made in writing within 30 days of the decision.

If you are not satisfied with the way we have handled your FOI request, you can lodge a complaint with the OAIC. However, the OAIC suggests that complaints are made to the agency in the first instance.

While there is no particular form required to make a complaint to the OAIC, the complaint should be in writing and set out the reasons for why you are dissatisfied with the way your request was processed. It should also identify the Department of Health and Aged Care as the agency about which you are complaining.

You can make an IC review application or make an FOI complaint in one of the following ways:

- online at www.oaic.gov.au/freedom-of-information/reviews-and-complaints/
- via email to foidr@oaic.gov.au
- by mail to GPO Box 5218 Sydney NSW 2001, or

- by fax to 02 9284 9666.

More information about the Information Commissioner reviews and complaints is available on the OAIC website here: www.oaic.gov.au/freedom-of-information/foi-review-process.

Complaint

If you are dissatisfied with action taken by the department, you may also make a complaint directly to the department.

Complaints to the department are covered by the department's privacy policy. A form for lodging a complaint directly to the department is available on the department's website here: www.health.gov.au/about-us/contact-us/complaints