



Australian Government

Department of Health and Aged Care

FOI reference: FOI 5155

Mr Ian Saunders

By email: foi+request-11435-579b94d9@righttoknow.org.au

Dear Mr Saunders,

Decision on your Freedom of Information Request

I refer to your request of 22 May 2024 to the Department of Health and Aged Care (the department), seeking access under the *Freedom of Information Act 1982* (Cth) (FOI Act) to:

All documents associated with MSAC 1530 - Purified human alpha1-proteinase inhibitor (A1-PI) for the treatment of alpha1-proteinase inhibitor deficiency, leading to chronic obstructive pulmonary disease (COPD).

Clarification of scope of request

On 29 May 2024 you clarified the scope of your request as follows:

The following documents associated with MSAC 1530 - Purified human alpha1-proteinase inhibitor (A1-PI) for the treatment of alpha1-proteinase inhibitor deficiency, leading to chronic obstructive pulmonary disease (COPD):

- 1. Grifols and CSL submissions*
- 2. The full Assessment Report related to the MSAC submission (around 2017 - 2018)*
- 3. The economic analysis carried out relating to cost/benefit of augmentation therapy*
- 4. The full (unredacted) public report "1530 - Purified human alpha1-proteinase inhibitor (A1-PI) for the treatment of alpha1-proteinase inhibitor deficiency, leading to chronic obstructive pulmonary disease (COPD) from 2018"*

Extensions of Time

Your request was originally due on 21 June 2024. On 13 June 2024 the department informed you that consultation with third parties would be necessary. Under the FOI Act this provided the department with an additional 30 days to process this request. Your request subsequently became due on 21 July 2024.

On 18 July 2024, the department contacted you seeking your agreement to extend your request under s15AA of the FOI Act by 21 calendar days. On same date you agreed to this extension, meaning your request then became due on 11 August 2024.

On 2 August 2024 the department contacted you seeking your agreement to further extend your request under s15AA. We requested an extension of 9 calendar days. On same date you agreed to this extension, meaning your request then became due on 20 August 2024.

FOI decision

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.

I have identified nine documents comprising of seven primary documents and two attachments 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 nine documents in part, subject to the deletion of exempt and irrelevant 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**.

You were informed on 13 June 2024 that consultation with third parties would be necessary. A contention has been made that documents 2 - 7 should be exempt in full from disclosure. My decision has been to grant access to that material in part. As such, the relevant third parties have review rights under the FOI Act.

As a result, I am unable to provide you with access to these documents until the third-party review rights have expired.

Legislative provisions

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

The *Privacy Act 1988* (Cth) (Privacy Act), can also be accessed from the Federal Register of Legislation website here: www.legislation.gov.au/Series/C2004A03712.

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



Caroline Turnour
Assistant Secretary
Office of Health Technology Assessment Branch
19 August 2024

ATTACHMENT A.

SCHEDULE OF DOCUMENTS
FOI-5155

Document	Pages	Date	Description	Decision on access	Relevant provisions of FOI Act
1	3	18/09/2018	1530 pre-ESC response	Release with exempt information deleted.	s45 s47G
1.1	2	18/09/2018	1530 Attachment to pre-ESC response in Document 1	Release in full.	
2	1	18/09/2018	1530 pre-ESC response Third-party review rights.	Release with exempt information deleted.	s47G
3	12	21/11/2018	1530 - Pre-MSAC response including emails Third-party review rights.	Release with exempt and irrelevant information deleted.	s22 s45 s47F s47G
3.1	48	13/11/2018	1530 - Pre-MSAC response attachment in Document 3. - Biochemical verification of tobacco use and cessation publication	Release with exempt information deleted.	s45
4	218	31/08/2018	1530 - Final Contracted Assessment Report - August 2018 Third-party review rights.	Release with exempt information deleted.	s45 s47(1)(b) s47F s47G
5	18	17/01/2019	1530 - Final Public Summary Document - November 2018 Third-party review rights.	Release with exempt information deleted.	s47(1)(b)
6	11	15/11/2018	1530 - Assessment Group additional analyses-Annex to Section D Third-party review rights.	Release with exempt information deleted.	s45 s47(1)(b) s47G
7	2	19/11/2018	1530 - Assessment Group further sensitivity analyses Third-party review rights.	Release with exempt information deleted.	s47(1)(b)

ATTACHMENT B.

**REASONS FOR DECISION
FOI-5155**

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 22 - deletion of irrelevant and exempt 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.

The documents contain the names and telephone numbers of Department of Health employees. When your request was acknowledged, we notified you that this material would be considered irrelevant to the scope of your request unless you told us that you were seeking access to that material. On the basis that you did not notify us otherwise, this information has been deleted under section 22 of the FOI Act as outlined above.

The pages of document 3 marked 's22' are irrelevant as they contain correspondence relating to administrative issues, namely the receipt of MSAC submissions. As you have not requested access to these documents, the department considers this irrelevant to the scope of your request.

As I have decided that some of the information in the documents released to you is exempt from disclosure, I have prepared an edited copy of the document(s) by deleting the exempt information from the documents under section 22 of the FOI Act as outlined above.

4. Section 45 - Documents containing material obtained in confidence

Section 45 of the FOI Act provides that a document is an exempt document if its disclosure would found an action by a person for breach of confidence.

Paragraph 5.189 of the FOI Guidelines states that to found an action for breach of confidence, the following five criteria must be satisfied in relation to the information:

- it must be specifically identified
- it must have the necessary quality of confidentiality
- it must have been communicated and received on the basis of a mutual understanding of confidence
- it must have been disclosed or threatened to be disclosed, without authority
- unauthorised disclosure of the information has or will cause detriment

I am satisfied that the parts of the documents marked 's45' consist of information:

- that is specifically identified within the documents as being confidential in nature
- that has the quality of confidentiality, is only known to a limited group and is not common knowledge nor in the public domain
- that was communicated and received on the basis of mutual understanding of confidence, and that this mutual understanding exists at the time of the communication
- in circumstances in which there is a contractual obligation of confidence between the department and an affected third party
- in circumstances in which disclosure of the information will be without the authority of the affected third party, and
- in circumstances where disclosure of the information would cause detriment to the party who provided the confidential information to the department. The detriment in this instance would involve financial loss to the affected third party.

Documents 1, 3, 3.1 and 6 contains information that was communicated to the department in confidence. The release of the information marked s45 would reasonably constitute a breach of confidence. The information, if released, would also undermine the third parties' competitive advantage and allow competitors to gain an unfair advantage in several global markets.

For the reasons outlined above, I have decided that the parts of the documents marked 's45' are exempt from disclosure under section 45 of the FOI Act.

5. Section 47 - Documents disclosing trade secrets or commercially valuable information

Subsection 47(1) of the FOI Act provides that a document is an exempt document if its disclosure 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.

Commercially valuable information

Paragraphs 5.234 and 5.235 of the FOI Guidelines state:

5.234 To be exempt under s 47(1)(b) a document must satisfy two criteria:

- the document must contain information that has a commercial value either to an agency or to another person or body, and
- the commercial value of the information would be, or could reasonably be expected to be, destroyed or diminished if it were disclosed

5.235 It is a question of fact whether information has commercial value, and whether disclosure would destroy or diminish that value. The commercial value may relate, for example, to the profitability or viability of a continuing business operation or commercial activity in which an agency or person is involved. The information need not necessarily have 'exchange value', in the sense that it can be sold as a trade secret or intellectual property. The following factors may assist in deciding in a particular case whether information has 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, if it 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

I am satisfied that the relevant information contained in the documents:

- is only known to the department and the affected third party for whom it has value

- is not known to others, and disclosure of the information would detract from its intrinsic commercial value
- confers a competitive advantage on the affected third party, and provides the affected third party with access to markets not available to its competitors
- is something that a genuine “arm’s length’ buyer would be prepared to pay to obtain
- is still current, and retains its intrinsic value to the affected third party
- would reduce in value to the business operations or commercial activities of the affected third party if disclosed.

Based on the above considerations, I am satisfied that documents 4 – 7 contain information that is commercially valuable to the affected third parties. This information if disclosed could reasonably impact the profitability and commercial viability of the third parties. Providing this information would allow an unfair advantage to the third parties competitors and customers.

As notified to you on 13 June 2024, in accordance with section 27 of the FOI Act, the department has consulted with affected third parties. In making my decision on access to the relevant documents, I have taken into consideration the exemption submissions made during that consultation process.

For the reasons outlined above, I have decided that the parts of the documents marked ‘s47’ are exempt from disclosure under section 47 of the FOI Act.

6. Section 47F – Documents affecting personal privacy

Section 47F of the FOI Act provides that a document is conditionally exempt if its disclosure would involve the unreasonable disclosure of personal information about any person (including a deceased person).

Personal Information

Personal information has the same meaning as in the Privacy Act. Specifically, section 6 of the Privacy Act provides that *personal information* means information or an opinion about an identified individual, or an individual who is reasonably identifiable whether the information or opinion is true or not; and whether the information or opinion is recorded in a material form or not.

Paragraph 6.123 of the FOI Guidelines states that for particular information to be personal information, an individual must be identified or reasonably identifiable:

- whether the information is true or not, and
- whether the information or opinion is recorded in a material form or not.

Paragraph 6.125 of the FOI Guidelines states that personal information can include a person’s name, address, telephone number, date of birth, medical records, bank account details, taxation information and signature.

Paragraph 6.132 of the FOI Guidelines states that an individual is a natural person and does not include a corporation, trust, body politic or incorporated association. Section 47F specifically extends to the personal information of deceased persons.

I am satisfied that the parts of the documents marked 's47F' includes personal information.

Unreasonable Disclosure of Personal Information

Subsection 47F(2) of the FOI Act provides that in determining whether the disclosure would involve the unreasonable disclosure of personal information, I 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.

Paragraph 6.133 of the FOI Guidelines states that:

The personal privacy exemption is designed to prevent the unreasonable invasion of third parties' privacy. The test of 'unreasonableness' implies a need to balance the public interest in disclosure of government-held information and the private interest in the privacy of individuals. The test does not, however, amount to the public interest test of s 11A(5), which follows later in the decision making process. It is possible that the decision maker may need to consider one or more factors twice, once to determine if a projected effect is unreasonable and again when assessing the public interest balance.

I note that the AAT, in *Re Chandra and Minister for Immigration and Ethnic Affairs [1984] AATA 437* at paragraph 51-52, stated that:

... whether a disclosure is 'unreasonable' requires ... a consideration of all the circumstances, including the nature of the information that would be disclosed, the circumstances in which the information was obtained, the likelihood of the information being information that the person concerned would not wish to have disclosed without consent, and whether the information has any current relevance ... it is also necessary in my view to take into consideration the public interest recognised by the Act in the disclosure of information ... and to weigh that interest in the balance against the public interest in protecting the personal privacy of a third party ...

Paragraphs 6.137 and 6.138 of the FOI Guidelines state:

6.137 Key factors for determining whether disclosure is unreasonable include:

- the author of the document is identifiable
- the documents contain third party personal information
- release of the documents would cause stress on the third party
- no public purpose would be achieved through release

6.138 As discussed in the leading s 47F IC review decision of 'FG' and National Archives of Australia [2015] AICmr 26, other factors considered to be relevant include:

- the nature, age and current relevance of the information
- any detriment that disclosure may cause to the person to whom the information relates
- any opposition to disclosure expressed or likely to be held by that person
- the circumstances of an agency's collection and use of the information
- the fact that the FOI Act does not control or restrict any subsequent use or dissemination of information released under the FOI Act
- any submission an FOI applicant chooses to make in support of their application as to their reasons for seeking access and their intended or likely use or dissemination of the information, and
- whether disclosure of the information might advance the public interest in government transparency and integrity

You have requested access to documents that contain personal information about a number of identifiable third parties.

I have reviewed the relevant parts of documents 3 and 4 and I am satisfied that the disclosure of personal information contained within these documents would, in the circumstances, constitute an unreasonable disclosure of personal information for the following reasons:

- the individuals whose personal information is contained in the documents are identifiable
- release of this information could reasonably be expected to cause anxiety to the individuals concerned
- no further public purpose would be achieved through the release of the personal information, noting that the personal information is included in the document as a result of their employment circumstance
- the information is current and has not lost its sensitivity through the passage of time
- the individuals would not expect the information to be placed in the public domain, and detriment may be caused to the individuals to whom the information relates, and
- the FOI Act does not control or restrict any subsequent use or dissemination of information released under the FOI Act.

In making my decision, I have consulted with the affected third parties regarding the disclosure of their personal information, and I have considered any concerns raised by those individuals.

For the reasons outlined above, I have decided that the parts of the documents marked 's47F' are conditionally exempt from disclosure under section 47F 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.

7. Section 47G - Business information

Section 47G of the FOI Act provides that a document is conditionally exempt if its disclosure 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 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.

Business information

Paragraph 6.177 of the FOI Guidelines states that the conditionally exempt information must have some relevance to a person in respect of his or her business or professional affairs or to the business, commercial or financial affairs of an organisation or undertaking.

Paragraph 6.191 of the FOI Guidelines states that the use of the term 'business or professional affairs' distinguishes an individual's personal or private affairs and an organisation's internal affairs. The term 'business affairs' has been interpreted to mean 'the totality of the money-making affairs of an organisation or undertaking as distinct from its private or internal affairs'.

Paragraph 6.193 of the FOI Guidelines states that 'profession' is not static, and is clearly intended to cover the work activities of a person who is admitted to a recognised profession and who ordinarily offers professional services to the public for a fee.

Documents 1, 3, 4 and 6 contain information that was communicated in confidence from businesses operating in a professional and/or commercial capacity. I am satisfied that the disclosure of this information would adversely affect the profitability and financial viability of third parties. In coming to this conclusion I have considered the third parties concerns and decided that the release of this information would likely cause the third parties to suffer both commercial and financial detriment.

In making my decision, I have consulted with the affected third party regarding the relevant business affairs information, and I have considered any concerns.

The parts of the documents marked 's47G' contain business affairs information that is relevant to the business, commercial or financial affairs of an organisation or undertaking. This information is relevant to the profitability and financial viability of an organisation or undertaking, and does not relate to its private or internal affairs.

Subsection 47G(2) of the FOI Act provides that subsection 47G(1) does not apply to trade secrets or other information to which section 47 applies. Section 47G has not been applied to any information which I have previously decided is exempt under section 47 of the FOI Act.

For the reasons outlined above, I have decided that the parts of the documents marked 's47G' are conditionally exempt from disclosure under section 47G 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.

8. 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.

Paragraph 6.227 of the FOI Guidelines states that:

'The pro-disclosure principle declared in the objects of The FOI Act is given specific effect in the public interest test, as the test is weighted toward disclosure. If a decision is made that a conditionally exempt document should not be disclosed, the decision maker must include the public interest factors they took into account in their statement of reasons...'

I have therefore considered the public interest factors favouring and against disclosure of the documents in my assessment.

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 inform debate on a matter of public importance
- would promote effective some limited oversight of public expenditure, and
- would not allow you access to your own personal information.

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:

s47F – personal privacy

- could reasonably be expected to prejudice the protection of the relevant individuals' right to personal privacy, noting that the substance of the documents has been released to you and disclosure of the personal information would not provide you with any further insight into the workings of government.
- would not achieve any public purpose and, on balance, would harm the individual's right to personal privacy.
- would be contrary to the objects of the Privacy Act.

s47G – business affairs

- could reasonably be expected to expose the business or commercial affairs of an Australian business to the world at large and adversely affect that organisation's current or future business and/or commercial opportunities. Any adverse impact on the contracted parties or supplies used by the department could reasonably be expected to reduce the pool of information and service available to the department, which would have adverse impacts on the ability of the department to source quality and cost-effective goods and services. Any impediment to the ability of the department to conduct its lawful affairs with quality and cost-effective business services would be contrary to the public interest.
- could reasonably be expected to prejudice the department's ability to obtain confidential information from contracted third parties and/or suppliers. Any impediment to the ability of the department to engage with contracted third parties and suppliers to progress the department's operations would be contrary to the public interest.

- could reasonably be expected to prejudice an agency's ability to obtain similar information in the future. Any impediment to the ability of the department to engage with contracted third parties and suppliers to obtain information that helps to inform the department's policy settings and operational outcomes would be contrary to the public interest.

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.

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 and Aged Care
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 review or complaint

You have the right to seek Information Commissioner (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