



Australian Government

Department of Health and Aged Care Therapeutic Goods Administration

Ragnar Lothbrok
Email: foi+request-10701-cc42b739@righttoknow.org.au

Dear Mr Lothbrok

FREEDOM OF INFORMATION REQUEST FOI 4722 Notice of Decision

- I refer to your request dated 20 September 2023 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

I would like to obtain a copy of the 26 page response from the Therapeutic Goods Association with regard to an application made by an ASX listed company called Rhythm Biosciences Ltd (ASX code RHY) and/or Vision Tech Bio Pty Ltd for a product called COLOSTAT (a Colorectal Cancer blood test) to be entered on the ARTG.. The lodgement date of the application was on or around 12 May 2022. The response from the TGA and subsequent withdrawal of application by Rhythm Biosciences Ltd and/or Vision Tech Bio Pty Ltd was on or around 6 March 2023.

I am still an investor in Rhythm Biosciences Ltd and the company has not disclosed why it withdrew its application in detail. Obtaining this 26 page report will allow me to re-evaluate my investment.'

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 one (1) document that falls within the scope of your request.

Background

- On 20 September 2023 the TGA received a request from you under the FOI Act.
- On 28 September 2023 the TGA acknowledged receipt of your FOI request. You were also advised at this time that I had decided not to impose any charges for the processing of your request.

Material Considered in Decision-Making

- In coming to my decision, I had regard to the following:
 - the correspondence between the TGA and yourself;
 - the document that falls within the scope of the FOI request;
 - the provisions of the FOI Act, in particular subsection 22(1), section 47 and paragraph 47G(1)(a) of the FOI Act;
 - the guidelines issued by the Office of the Australian Information Commissioner (OAIC) under section 93A of the FOI Act; and
 - consultation with third parties whose document is involved.

Decision

7. My decision in relation to the document that falls within the scope of your FOI request is to release in part.
8. My decision not to provide you with full access to the documents is based on the application of section 47 and paragraph 47G(1)(a) of the FOI Act.
9. As outlined in paragraph 5 of this letter, I have decided to waive the charges for processing your request in full noting that this request was subject to a previous matter in which a decision had been provided.
10. Therefore, as my decision is to waive the charges in full, the document can now be released to you.

Reasons for Decision

Relevant Documents

11. One document has been identified as relevant to your request. A schedule listing the document along with the document is at **Attachment A**.
12. The schedule indicates my decision to release in part, and refers to the exemption provisions which are claimed to apply to the document.
13. Under subsection 22 of the FOI Act, irrelevant information has been redacted from the document as it is considered to be outside the scope of your request.
14. The reasons for the application of these exemption provisions to the document 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

15. 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**.
16. The relevant document contains information that does not fall within the scope of your FOI request. Specifically, the document contains personal information such as individual's names, phone numbers and email addresses, which you confirmed are not part of your request.
17. I consider that to provide you with full access to the document would disclose the above information that does not fall within the scope of your FOI request. Accordingly, I have decided that the irrelevant information will be deleted under section 22(1) of the FOI Act and a copy of the document, with the irrelevant information deleted, will be provided to you.

Section 47: Documents are exempt documents if they contain a trade secret

18. Under section 47 of the FOI Act, a document is an exempt document if it contains a trade secret (paragraph 47(1)(a)) or contains information that has commercial value that could reasonably be expected to be destroyed or diminished if it were disclosed (paragraph 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 paragraph 47(1)(b) is at **Attachment B**.

19. Paragraph 5.205 of the Information Commissioner 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.
20. Having regard to the submissions of the third parties (in which they have requested that formulations, methodologies, algorithms, dilutions and calibrations be exempt from release), and taking into account the FOI Guidelines, I am satisfied the information contained in Document 1 that identifies the formulations used to develop Rhythm Bioscience’s (*Rhythm*) products is commercially valuable information, the value of which would be diminished or destroyed if disclosed, for the following reasons:
- The information regarding the production of Rhythm’s product is kept secure and tightly controlled and is only revealed to key representatives of Rhythm based on a need-to-know basis.
 - The use and formulation of the technology that Rhythm uses, along with identifying Global Medical Device Nomenclature (GMDN) codes, is not yet publicly known. If a competitor became aware of this classification, it may identify the classification of the product in question which would provide the competitor with an unfair advantage in reproducing this product.
 - The information contained in Document 1 constitutes Rhythm’s intellectual property and is considered commercially valuable. Rhythm’s intellectual property is proprietary as it evidences the steps taken to develop and produce the ColoSTAT product and is not known to the general public.
 - I am satisfied that a competitor to Rhythm would be prepared to obtain the information contained in Document 1 to assist in submitting its own application, and further that a competitor of Rhythm would use this information to gain an unfair advantage over Rhythm in the market of medical device development.
21. If the information in Document 1 over which Rhythm sought an exemption under section 47 was disclosed to a competitor, Rhythm would be significantly disadvantaged. A competitor could use the trade secrets to significantly accelerate development of competing products and improve their competitive position and thereby diminish Rhythm’s position in the marketplace.
22. Therefore, I am satisfied that the information is of a commercial value to Rhythm, the value of which would be diminished or destroyed if released, and accordingly I am satisfied that such information is exempt under section 47 of the Act.

23. Accordingly, part of Document 1 (as identified in the schedule at **Attachment A**) is exempt under paragraph 47(1)(b) of the FOI Act and has been deleted from the document.

Paragraph 47G(1)(a) – unreasonable adverse effect on business affairs

24. A document is conditionally exempt under paragraph 47G(1)(a) of the FOI Act where disclosure of information concerning the business affairs of an organisation would, or could reasonably be expected to, unreasonably affect the person adversely in respect of their business affairs. A copy of paragraph 47G(1)(a) is at **Attachment B**.

25. I am satisfied that Document 1 contains information regarding the business affairs of Rhythm. Specifically, Document 1 contains information regarding assessment of risk factors relating to the product which, if publicly released without any context could cause loss of reputation.

26. Further, Document 1 contains detailed information regarding potential identified risks which are still under development. If that information was to be disclosed, it would have a detrimental effect on Rhythm's commercial and financial affairs. In addition to this, the disclosure of such information may cause consumers to perceive that there may be risks and safety concerns associated with the ColoSTAT product which could affect future marketability of the product.

27. For the information to be considered exempt under paragraph 47G(1)(a), any adverse effects on the business affairs of Rhythm must be "unreasonable".

28. In determining whether any adverse effect is 'unreasonable', it is necessary to undertake a balancing of relevant interests.

29. The FOI Guidelines provide an example of where there may be public interest grounds to disclose the information, notwithstanding that the affairs of a business or person may be adversely affected. Specifically, the FOI Guidelines provide the example of when information regarding a business's activities pose a threat to public safety – in such circumstances it may be reasonable to disclose the information even though it may well have an adverse affect on the affairs of that business.

30. In this specific case, I am satisfied that it would be unreasonable to disclose information regarding risk factors relating to the product, as I consider disclosure of this information would have an adverse effect on the business. I am also satisfied that there is no overarching public interest of the kind referred to in the FOI Guidelines that would make such disclosure justified and reasonable.

31. Further, I am satisfied that information outlined above is conditionally exempt under paragraph 47G(1)(a) as disclosure would, or could reasonably be expected to, unreasonably affect Rhythm in respect of their professional and commercial affairs. 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.

32. In relation to the factors favouring giving access to the information, I have considered the following:

- the general public interest in obtaining access to government-held information;
- the objects of the FOI Act which encourages access to information held by government agencies, subject only to certain exemptions; and

- the public interest in ensuring the integrity and viability of the regulatory/registration process of the TGA regarding medical devices.

33. In relation to the factors against giving access to the information, I have considered the following:

- the public interest in preserving confidentiality having regard to the sensitivity of the information and the circumstance in which the information was communicated to the TGA, specifically in this case, Rhythm's application for a new medical device;
- the public interest in ensuring that persons or organisations continue to actively volunteer information to the TGA despite the fact that the information may be sensitive to their business and commercial affairs. In this case, the additional information requested by the TGA for Rhythm to provide further context on the formulation of their patented product;
- the disclosure of this information without context provides an opportunity for competitors to commercialise the 'ineffectiveness' of the ColoSTAT product;
- the public interest in encouraging and ensuring that companies continue to develop and register new therapeutic goods that would benefit the public.

34. On balance, I consider that giving access to the information at this time would be contrary to the public interest.

35. For the reasons set out above, I have decided not to disclose some of the information contained within Document 1 (as identified in the schedule at **Attachment A**).

Release of Documents

36. As the charges associated with processing your request have been waived in full, the document is now being released to you.

Review and Complaint Rights

37. If you are not satisfied with this decision, you have 30 calendar days to either seek internal review or apply to the OAIC for review of the decision. Further information can be found on the OAIC website at the following link: www.oaic.gov.au/freedom-of-information/your-freedom-of-information-rights/freedom-of-information-reviews

If you have any queries regarding this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

Pierre Nijssen
Director – Devices Business Support Section
Medical Devices Authorisation Branch
Therapeutic Goods Administration
4 October 2023

Schedule of Relevant Documents

Doc. No.	Author	Addressee	Date	Description	Pages	Decision	Relevant Sections of the Act
1	TGA	Sponsor	16/3/23	Email for request for additional information for device application	30	Release in part	s22 s47 s47G



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.

17 Requests involving use of computers etc.

- (1) Where:

- (a) a request (including a request in relation to which a practical refusal reason exists) is made in accordance with the requirements of subsection 15(2) to an agency;
- (b) it appears from the request that the desire of the applicant is for information that is not available in discrete form in written documents of the agency; and
- (ba) it does not appear from the request that the applicant wishes to be provided with a computer tape or computer disk on which the information is recorded; and
- (c) the agency could produce a written document containing the information in discrete form by:
 - (i) the use of a computer or other equipment that is ordinarily available to the agency for retrieving or collating stored information; or
 - (ii) the making of a transcript from a sound recording held in the agency;
 the agency shall deal with the request as if it were a request for access to a written document so produced and containing that information and, for that purpose, this Act applies as if the agency had such a document in its possession.

- (2) An agency is not required to comply with subsection (1) if compliance would substantially and unreasonably divert the resources of the agency from its other operations.

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.

42 Documents subject to legal professional privilege

- (1) A document is an exempt document if it is of such a nature that it would be privileged from production in legal proceedings on the ground of legal professional privilege.
- (2) A document is not an exempt document because of subsection (1) if the person entitled to claim legal professional privilege in relation to the production of the document in legal proceedings waives that claim.
- (3) A document is not an exempt document under subsection (1) by reason only that:
 - (a) the document contains information that would (apart from this subsection) cause the document to be exempt under subsection (1); and
 - (b) the information is operational information of an agency.

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.

47B Commonwealth-State relations etc

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

- (a) would, or could reasonably be expected to, cause damage to relations between the Commonwealth and a State (including a Territory)

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).