



Australian Government
Department of Health
Therapeutic Goods Administration

TRIM: [D22-5090793](#)

Jaay-H

Email: foi+request-8208-8ae5bbf1@righttoknow.org.au

Dear Jaay-H

FREEDOM OF INFORMATION REQUEST FOI 3520
Notice of Decision

1. I refer to your request dated 17 December 2021 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

"The Australian public have a right to know the number of serious adverse events reported following covid-19 vaccine injections. The public interest underpinning this request is clear and profound.

The department and TGA are not disclosing this information of their own volition and it is more than reasonable to contend that the public may require this information to make informed decisions and to provide informed consent. Please accept this request for information in accordance with the FOI Act.

a) Please provide a document recording the number of serious adverse events reported following covid-19 vaccine injection correct up until 17 December 2021.

b) Please also provide a document recording the number of serious adverse events reported in persons under the age of 18 correct up until 17 December 2021.

I contend that the public interest is sufficient for the agency to release these documents without charge."

Decision Maker

2. 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

3. The TGA has created one document in accordance with section 17 of the FOI Act.

Background

4. On 17 December 2021 the TGA received a request from you under the FOI Act. You also advised at this time that you were seeking a waiver of charges on public interest grounds.
5. On 10 January 2022 you were advised that the cost of processing your request amounted to \$15.00 and you were asked to pay the full amount of \$15.00. You were also asked to confirm in writing if you still intended to seek a waiver of the charges, and you were asked to provide any additional information you would like the TGA to consider in support of your claim.

6. On 16 January 2022 you advised that you will pay the \$15.00 in full (and therefore would not be seeking a waiver of charges).
7. On 31 January 2022 the TGA received payment in the amount of \$15.00 for the processing of your request.

Material Considered in Decision-Making

8. In coming to my decision, I had regard to the following:
 - the correspondence between the TGA and yourself, including the terms of your FOI request;
 - the document relevant to the scope of your request;
 - the provisions of the FOI Act, in particular section 17 of the FOI Act; and
 - the guidelines issued by the Office of the Australian Information Commissioner (OAIC) under section 93A of the FOI Act.

Decision

9. My decision in relation to the document created in accordance with section 17 of the FOI Act is to release 1 document in full.
10. The preliminary estimate of charges associated with processing this FOI request was \$15.00. This amount includes the first five hours of decision making at no cost. In accordance with the *Freedom of Information (Charges) Regulations 2019* (the Charges Regulations) I have calculated the actual charges that can be imposed for processing your request. In this case, the actual charges that can be imposed are \$15.00. As my decision is to give you full access to the document, I have decided to impose the actual charges associated with processing your request.
11. Therefore, as you have already paid the estimate of \$15.00 in full, the document is now being released to you.

Reasons for Decision

Relevant Documents

12. One document has been created in accordance with section 17 of the FOI Act. A schedule listing the document is at **Attachment A**.

Section 17 Requests involving use of computers etc.

13. Section 17 of the FOI Act provides that an agency must produce a written document containing information that is stored electronically and not in a discrete written form, if:
 - it does not appear from the request that the applicant wishes to be provided with a computer tape or disk on which the information is recorded;
 - the agency could produce a written document containing the information by the use of a computer or other equipment ordinarily available to the agency; and
 - producing such a document would not substantially and unreasonably divert the resources of the agency from its other operations.
14. In this instance, the information you have sought is not available in discrete form in written documents held by the TGA. However, the TGA was able to produce a written document containing the requested information in discrete form by the use of a computer or other equipment available to the TGA. The TGA has therefore, in this particular instance, created a document under section 17 of the FOI Act.

Release of Documents

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

Review and Complaint Rights

16. If you are not satisfied with this decision, you can 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/reviews-and-complaints/

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

Yours sincerely

Signed electronically

Dr Claire Larter
Director
Pharmacovigilance Branch
Therapeutic Goods Administration
3 February 2022

FOI Request 3520 in relation to Adverse Event Reports**Schedule of Relevant Documents**

| Doc. No. | Author | Date | Description | Pages | Decision | Relevant Sections of the Act |
|-----------------|---------------|-----------------|---|--------------|-----------------|-------------------------------------|
| 1 | TGA | 31 January 2022 | Number of serious adverse events reported up until 17 December 2021 | 1 | Release in full | |



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.

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).