Australian Government
Department of Health
Therapeutic Goods Administration

[redacted]

Our reference: LEX25178

Dear Dr [redacted]

**FREEDOM OF INFORMATION REQUEST FOI 2565**

**Notice of Internal Review Decision**

1. I refer to your request for internal review dated 4 September 2021 of Mr Michael Wiseman's access refusal decision dated 26 August 2021 under section 24 of the *Freedom of Information Act 1982* (**the FOI Act**).
2. In particular, I note that you are seeking access to three toxicology studies that consider the histopathology and microscopic evaluation of animals vaccinated with COVID-19 vaccines.
3. Two of these studies relate to the Pfizer COVID-19 vaccine, and the third relates to the AstraZeneca COVID-19 vaccine. You are seeking access to these studies in their entirety, which comprise a combined total of 3,667 pages.

**Decision maker**

4. I am the Therapeutic Goods Administration (**TGA**) officer authorised to make this internal review decision under section 23 of the FOI Act.

**Decision**

5. I agree with the initial decision dated 26 August 2021. I am therefore writing to advise you of my decision under the FOI Act to refuse access to the documents that are the subject of your request.
6. I am satisfied that a practical refusal reason still exists in relation to your request. The work involved in processing your request would substantially and unreasonably divert the TGA's resources from its operations.
7. The reasons for my decision are set out in further detail below.

**Background**

8. The relevant background to your request for internal review is set out below.

***Freedom of Information request***

9. On 29 July 2021, the TGA received a request from you under the FOI Act for the following documents:

> *"All Developmental and Reproductive Toxicity Studies available to the TGA regarding the Pfizer and AstraZeneca COVID-19 vaccines including histology reports of gonads of vaccinated animals".*

***Request consultation process***

10. On 11 August 2021, Mr Wiseman wrote to advise you of his intention to refuse to provide you with access to the documents within the scope of your request. This was based on the fact that your request would involve the review and consideration of 11 documents that contained a total of 5,708 pages, and that this would create an unreasonable diversion of the TGA's resources.

11. As required by subsection 24(1)(a) of the FOI Act, a request consultation process commenced in accordance with section 24AB of the FOI Act, with a view to giving you an opportunity to revise the scope of your request so that a practical refusal reason might no longer exist.

12. In doing so, Mr Wiseman also provided you with publicly available information in relation to the developmental and reproductive toxicity studies, as well as other publicly available resources to support the safety and efficacy of COVID-19 vaccines approved for use in Australia.

13. On 21 August 2021, you emailed the TGA to confirm that you would revise the scope of your request under the FOI Act for the following documents:

    *"Histopathology/microscopic evaluation of gonads (ovaries/testes) of vaccinated animals in relation to Pfizer and AstraZeneca COVID-19 vaccines"* (**your revised FOI request**).

***Initial decision***

14. On 26 August 2021, Mr Wiseman notified you of his decision under section 24 of the FOI Act to refuse access to the documents identified as falling within the scope of your revised FOI request (**the initial decision**).

15. Whilst acknowledging that three, rather than 11, toxicology studies now fell within the scope of your revised FOI request (namely, two studies relating to the Pfizer vaccine, and the third relating to the AstraZeneca vaccine), Mr Wiseman determined that your request remained too voluminous to process, noting, in particular, that:

    - the three studies comprised a total of 3,667 pages;
    - that there was no way to extricate the information relating to the histopathology and microscope evaluation of the ovaries and testes of the animals as this information was intermingled throughout the studies and so the studies in their entirety would need to be considered; and
    - the TGA would be required to consult with Pfizer and AstraZeneca in relation to their respective studies.

16. The reasons for Mr Wiseman's decision are set out in further detail in paragraphs 19 – 30 of his decision dated 26 August 2021.

***Request for internal review***

17. On 4 September 2021, you requested internal review of the initial decision, for the reasons set out below:

    *"This communication is to request a formal internal review of the refusal of my FOI request 2565. I requested access to histopathology (also known as microscopy or histology) reports of ovaries and testes of COVID-19 vaccinated animals who had received either BNT162b2 (Pfizer) or ChAdOx-1 (AstraZeneca) provisionally licensed for use in Australia:*

*'Histopathology/microscopic evaluation of gonads (ovaries/testes) of vaccinated animals in relation to Pfizer and AstraZeneca COVID-19 vaccines.'*

*The above information is requested by myself as a reproductive health clinician and an accredited COVID-19 vaccine provider giving information to reproductive aged women and men in this context for informed consent to COVID-19 vaccination.*

*This histopathology report for BNT162b2 vaccine exists as discussed in the published preclinical study on page 33 of CJ Bowman et al, 'Lack of Effects on Female Fertility and Prenatal and Postnatal Offspring Development in Rats with BNT162b2, a mRNA-based COVID-19 Vaccine' (2021) 103 Reproductive Toxicology 28-35 (published online, 28 May 2021) https://doi.org/10.1016/j.reprotox.2021.05.007.*

*It is also referred to in 'Pre-Submission Meeting Briefing Document COVID-19 Vaccine (BNT162, PF-07302048)' 18th September 2020, and in 'Investigator's Brochure' 12th August 2020, though is not visible within these documents.*

*There is additional information upon which this formal review is requested:*

1. *There have been thousands of notifications to regulatory bodies of new onset menstrual irregularities and of new onset postmenopausal bleeding following both the AstraZeneca vaccine (Yellow Card Reporting System) and the Pfizer vaccine (Vaccine Adverse Event Reporting System) as of August 31st 2021.*
2. *The accessed Australian Government, Department of Health, Therapeutic Goods Administration, 'Non-clinical Evaluation Report BNT162b2 [mRNA] COVID-19 Vaccine (ComirnatyTM)' January 2021, FOI 2389 Document 6, Submission PM-2020-05461-1-2, states the concentration of labelled mRNA vaccine nanoparticles in rat ovaries is measured at 10x the concentration of nanoparticles in all other organs, with the exception of liver, spleen, adrenals and lymph tissue. This followed injection of the rats with a 50 microgram dose of BNT162b2. Fully vaccinated persons receive two 30 microgram doses.*
3. *The polyoxyethylene sorbitan monooleate (polysorbate 80) present in AstraZeneca vaccine (amount not identified in Product Information) resembles the endocrine disruptor diethylstilboestrol when injected into young rats (M Gajdova et al, 'Delayed Effects of Neonatal Exposure to Tween 80 on Female Reproductive Organs in Rats' (1993) 31 Food Chemical Toxicology 183), and is chemically related to polyethylenegycol in BNT162b2.*
4. *COVID-19 vaccines are now being mandated for several occupational sectors predominantly staffed by young reproductive aged men and women.*

*Vaccine confidence in these reproductive aged men and women would be assisted by transparency and full disclosure of the requested preclinical gonad histopathology. Informed consent also requires access to all information that could be considered relevant to the health and wellbeing of the recipient. The success of the vaccine roll out programme may be enhanced by provision of the requested information, particularly for those who may be experiencing some hesitancy in this domain of their future health."*

***Further consultation***

18. On 16 September 2021, the TGA FOI team emailed to advise you that, whilst noting that they could not pre-empt my decision on internal review, I had indicated a preliminary view that your request remained too voluminous to process.

19. Accordingly, and with a view to assisting you to further revise your request so that a practical refusal reason would no longer exist, the TGA FOI team suggested that you consider withdrawing your request for internal review, and submitting a new FOI request for the following documents:

> *"the written components of the three studies in relation to histopathology/microscopic evaluation of gonads (ovaries/testes) of vaccinated animals in relation to Pfizer and AstraZeneca COVID-19 vaccines, excluding personal information, appendices, annexures and raw data".*

20. In particular, the TGA FOI team indicated that the benefit in proceeding with the TGA's suggested scope would be that the number of pages to be processed for the three toxicology studies be reduced from 3,667 pages to approximately 210 pages.

21. On 20 September 2021, you confirmed that you wished to proceed with your request for internal review of the initial decision, for the following reasons:

> *"I confirm I would like to proceed with the internal review please. Particularly in the light of recent press coverage of reproductive health issues associated with COVID vaccination, I am keen to progress this request to enable me to respond as soon as I can to patient requests for more information."*

**Material Considered in Decision-Making**

22. In coming to my decision, I have had regard to the following:

- the terms of your FOI request and subsequent correspondence between you and the TGA, as set out in the background above, including:
    - the initial decision dated 26 August 2021;
    - your request for internal review dated 4 September 2021;
- the TGA's assessment of the time and resources that would be required to process your request, including the information I have received from the relevant area of the TGA concerning the resources required to comply with your request, and the effect of same on the TGA's operations;
- the documents falling within the scope of your request, including the time that would be involved to consult with the two third parties;
- the relevant provisions of the FOI Act, in particular sections 24, 24AA and 24AB; and
- the Freedom of Information Guidelines issued by the Information Commissioner (**the FOI Guidelines**) under subsection 93A(1) of the FOI Act, which I am required to have regard to under subsection 93A(2) of the FOI Act.

**Reasons for Internal Review Decision**

23. Notwithstanding the steps you have previously taken to revise the scope of your FOI request, I am of the view that your request remains too voluminous to process, and have decided to refuse access to the documents under section 24 of the FOI Act.

24. I have made this decision on the basis that a practical refusal reason exists within the meaning of subsection 24AA(1)(a)(i) of the FOI Act. That is, I am satisfied that the work involved in processing your request would substantially and unreasonably divert the resources of the TGA from its other operations.

25. Subsection 24AA(3) of the FOI Act sets out the matters to which I must not have any regard and, as such, I confirm that I have not had regard to any of those matters in making my decision. A copy of the relevant provisions of the FOI Act are at **Attachment A**.

***Scope of work required to process your request***

26. As set out in Mr Wiseman's decision dated 26 August 2021, the TGA has identified three toxicology studies that consider the histopathology and microscopic evaluation of animals in relation to the COVID-19 vaccines, and which therefore fall within the scope of your revised request.

27. Two of these are Pfizer studies (603 pages and 2,237 pages, respectively) and the third is an AstraZeneca study (827 pages). I consider the nature of the information in these unpublished studies to be relevant, in that the documents contain specific processes, materials, methods and designs used to carry out the studies, as well as comprehensive data relating to the statistical analysis and results.

28. Having reviewed the studies, and noting your email dated 21 August 2021, I confirm that it is not correct to suggest that the histopathology in relation to reproductive tissues in these studies is contained within "*a few pages*". As Mr Wiseman advised in his decision dated 26 August 2021, this information is dispersed throughout each of the studies, and is presented in such a way that it would be impractical to simply extract the relevant pages from the studies. Instead, it would be necessary to review and determine whether to refuse or grant access to an edited copy of each of the 3,667 pages in the three documents.

29. I also note that the TGA would need to consult a number of third parties (including Pfizer and AstraZeneca, in addition to their respective international counterparts) and obtain any submissions they may wish to make concerning the release of the documents. This is particularly so given that Pfizer and AstraZeneca provided these studies to the TGA in confidence as part of their applications for provisional registration of their respective vaccines.

30. The documents are likely to require numerous redactions as the documents are unpublished studies that contain information that is commercially sensitive and valuable. In this respect, I consider it significant that the data is not publicly available.

31. I am satisfied that both have taken active steps to ensure the information contained within the documents is not disclosed to the general public (or their competitors). I am therefore satisfied that the relevant information possesses an intrinsic commercial value that has not been diminished by disclosure to others.

***Estimate of the work involved to process the request***

32. I wish to provide an estimate of the time to process the three studies of 3,667 pages based on the TGA's commonly used 'charges calculator'. The charges calculated contains a number of predetermined parameters based on assumptions as to how long an FOI request should take to process. The calculator estimated 20% of pages would be disclosed as a whole and 80% of the pages would require redaction (in whole or part), and that at least two third parties would need to be consulted.

33. The calculator estimates the decision-making processing time. The decision-making process included an estimated timeframe for examining pages, consulting with third parties and writing the statement of reasons. The estimated total processing time determined by the calculator is **227.03 hours** (after deduction of the first five hours free).

***Sample of the documents***

34. Paragraph [3.121] of the FOI Guidelines relevantly states:

> *"An estimate of processing time is only one consideration to be taken into account when deciding whether a practical refusal reason exists. It is recommended that agencies examine a sample of the documents to assess the complexity of the material against whether the work involved in processing the request would constitute a substantial and unreasonable diversion of resources from the agency's other operations. A representative sample of between 10 to 15% of the documents within the scope of the request has been considered to be an appropriate sample size for the purposes of calculating processing time when deciding whether a practical refusal reason exists. A person with appropriate knowledge or expertise should assess the sample of the documents, looking at each document as if they were making a decision on access, including indicating the number of documents that could be released in an edited form"*.

35. Accordingly, I have asked a technical expert from the TGA's Scientific Evaluation Branch to review a sample of 10 – 15% of each of the three studies identified as falling within the scope of your request. Based on this review, the technical expert has calculated a conservative estimate of at least 30 hours as being required for the technical expert to simply review and edit (as necessary) the 3,667 pages in entirety.

36. This sample estimate does not reflect the time already spent on your request, including the time taken by the TGA's Scientific Evaluation Branch to identify the documents and conduct a brief review of the documents to determine whether the documents fell within the scope of your request.

37. The estimate also does not include the time that would be required for lawyers within the Regulatory Legal Services Branch of the TGA to review the documents and identify any applicable exemptions under the FOI Act. Nor does it include the time required for the TGA FOI team to apply redactions to the exempt information in the documents.

38. Lastly, the sample estimate does not take into consideration the time that would be required to consult the third parties, settle and make copies of the documents, and to prepare the decision letter and third-party decision letters and schedules.

***Substantial and unreasonable diversion of the TGA's resources***

39. Accordingly, I am of the view that the resources required to process your request significantly outweigh the public interest in releasing the three studies in their entirety. This is particularly so given that technical experts from the Scientific Evaluation Branch would be diverted from the performance of their primary role, which includes engaging in safety monitoring of medicines and vaccines, as well as the associated regulatory actions.

40. In this regard, I note that analysis and investigation of medicine and vaccine safety issues are of significant importance to public health and safety and are particularly crucial within the current context of the COVID-19 pandemic.

41. I also note that processing your request would necessitate the diversion of resources from a range of other business support areas within the TGA, including the Regulatory Legal Services Branch and the Reporting & Collaboration Services Section, the latter of which is the section responsible for processing FOI requests. As I am sure you will appreciate, these teams are also currently dealing with a high volume of COVID-19 FOI requests.

42. In this regard, the FOI Guidelines state that a relevant matter in deciding whether a practical refusal reason exists is *"the impact that processing a request may have on other work in the agency or minister's office,* ***including FOI processing"*** **(my emphasis)** (see paragraph 3.117 of the FOI Guidelines).

43. Based on the estimated hours it would take to process your request, and the need to involve staff from the TGA's specialist technical areas to assist in processing the request, I am satisfied that your request would substantially and unreasonably divert the TGA (as part of the Department of Health) from its other operations. It is also likely to cause serious delays to, and potentially compromise, the TGA's performance of its regulatory functions under the *Therapeutic Goods Act 1989.*

***Public interest in disclosure***

44. Paragraph [3.117] of the FOI Guidelines states that, when deciding whether a practical refusal reason exists in relation to an FOI request, a matter that may be relevant is whether there is significant public interest in the documents requested and what information is publicly available.

45. I also note that your request for internal review included that there is public interest in giving this information *"to reproductive aged women and men in this context for informed consent to COVID-19 vaccination"* and that *"vaccine confidence in these reproductive aged men and women would be assisted by transparency and full disclosure of the requested preclinical gonad histopathology […] The success of the vaccine roll out programme may be enhanced by provision of the requested information, particularly for those who may be experiencing some hesitancy in this domain of their future health."*

46. In this respect, I acknowledge that there is public interest in the release of evidence that supports the safety and efficacy of COVID-19 vaccines approved for use in Australia, and I agree with the assertion in your email dated 4 September 2021 that the success of the vaccine roll out program may be enhanced by the release of such information.

47. However, as mentioned in Mr Wiseman's request consult letter dated 11 August 2021 and his initial decision dated 26 August 2021, there is already a number of publicly available resources

that demonstrate the safety and efficacy of the Pfizer and AstraZeneca COVID-19 vaccines, including in the context of male and female fertility and reproductive health, such as:

- Lancet website contains further information on the Pfizer and AstraZeneca studies: https://www.thelancet.com/coronavirus/collection?SeriesKey=lancet&startPage=0&pageSize=100
- Shimabukuro TT et al, N Engl J Med 2021; 384:2273-2282;
- two studies in the American Journal of Obstetrics and Gynaecology:
    - www.ajog.org/article/S0002-9378(21)00187-3/fulltext
    - www.sciencedirect.com/science/article/pii/S0002937821000776
- a review in the journal Nature: www.nature.com/articles/s41577-021-00525-y.pdf
- Gonzalez DC, Nassau DE, Khodamoradi K, et al., 2021. Sperm Parameters Before and After COVID-19 mRNA Vaccination, JAMA, https://jamanetwork.com/journals/jama/fullarticle/2781360
- https://www.health.gov.au/news/joint-statement-between-ranzcog-and-atagi-about-covid-19-vaccination-for-pregnant-women
- https://www.health.gov.au/sites/default/files/documents/2021/06/covid-19-vaccination-shared-decision-making-guide-for-women-who-are-pregnant-breastfeeding-or-planning-pregnancy-covid-19-vaccination-shared-decision-making-guide-for-women-who-are-pregnant-breastfeeding-or-planning-pregna.pdf
- documents released in response to FOI request 2389 (documents relating to the evaluation of the Pfizer COVID-19 vaccine) and FOI request 2183 (clinical trial results relating to the Pfizer and AstraZenca COVID-19 vaccines). These documents are available on the TGA FOI disclosure log at https://www.tga.gov.au/foi-disclosure-log.
- the Product Information (PI) and Australian Public Assessment Reports for prescription medicines for information on adverse events which were observed in the clinical trials, as well as those observed from post-market surveillance and the in-depth descriptions of the clinical trial methodologies and outcomes for the correspondence vaccines, available here:
    - https://www.tga.gov.au/product-information-0;
    - https://www.tga.gov.au/ws-auspar-index; and
    - https://www.tga.gov.au/covid-19-vaccine-provisional-registrations.

48. I also wish to note, in response to your comment: *"there have been thousands of notifications to regulatory bodies of new onset menstrual irregularities and of new onset postmenopausal bleeding following both the AstraZeneca and Pfizer vaccine",* that the TGA publishes a weekly safety report for COVID-19 vaccines and makes adverse event information available to the public through the Database of Adverse Event Notifications – medicines (**DAEN**). All weekly safety reports remain available on the TGA website at this address: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report.

49. You can search the DAEN for "COVID" in the medicines report section, available here: https://apps.tga.gov.au/PROD/DAEN/daen-report.aspx. Once you have typed the first three letters of a medicine name, a list of trade names will appear with the active ingredients shown in brackets. Where the reporter has only provided the TGA with the active ingredient name, the database will display 'Tradename not specified'. Select the medicines you want to search for by

ticking or unticking the boxes. For example, to conduct a search by active ingredient, tick the box for each trade name containing the active ingredient.

50. There are two types of results shown in two tabs: medicine summary (this summary groups reported adverse events together) and list of reports (this lists all relevant reports in chronological order). In the "list of reports" tab when you search for the COVID-19 vaccine, the results table provides the case number, report entry date, the age of the person, gender, medicines reported as being taken and the reaction, so you could search for reports of menstruation and vaginal bleeding.

51. The TGA is committed to the transparent and accurate reporting of adverse events. I note that an adverse event report does not mean that the medicine is the cause of the adverse event.

52. As of 19 August 2021, the TGA has reduced the time between adverse event reports being accepted into our database and published on the DAEN from 90 days to 14 days. This decision was made in response to the strong public interest in adverse event reports relating to COVID-19 vaccinations and makes reports for vaccines publicly available more quickly.

53. Similar adverse event data is also made available by international regulators, for example:

    - The US Food and Drug Administration's Vaccine Adverse Event Reporting System: https://vaers.hhs.gov/
    - The UK Medicines and Healthcare products Regulatory Agency's Yellow Card reporting: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions
    - The European Medicines Agency EudraVigilance (European database of suspected adverse drug reaction reports): https://www.adrreports.eu/en/

54. I also note that AusVaxSafety is an active vaccine safety surveillance system that complements the TGA's enhanced safety surveillance activities. Active vaccine safety surveillance uses SMS and a short survey to collect reports of AEFI directly from a subset of people receiving the vaccines. AusVaxSafety is an Australian Government-funded system that shares its findings with the TGA to assist safety investigations and responses. Please see details of AusVaxSafety's latest COVID-19 safety data available here: https://www.ausvaxsafety.org.au/safety-data/covid-19-vaccines

55. I also agree with Mr Wiseman's findings in the initial decision that it is not appropriate to compare the information released in FOI request 2389 and FOI 2183 to surmise what is contained in the three studies. Whilst the documents released in relation to those FOI requests do contain some general information about the toxicology studies, those documents do not contain all the information on those studies (in particular, those documents do not include the comprehensive data relating to the statistical analysis and results).

56. Furthermore, those documents were made publicly available under the FOI Act in response to FOI requests 2389 and 2183 and the TGA considered each page of each document to determine whether the information had commercial value (for example) and had to consult the third parties in relation to the documents.

57. As you will see from the documents available on the TGA's disclosure log, those documents were released in part with certain information exempt under sections 22, 47, 47E(d) and 47G(1)(b)

of the FOI Act. Due to the size of the three studies, it would be too onerous for the TGA to undertake the same process in relation to this request.

58. Therefore, I consider that insofar as any interest is served by the release of the documents in question, the public interest in evidence supporting the safety and efficacy of COVID-19 vaccines in Australia has already been met through the publication of the supporting regulatory documents, in addition to the publicly available links referred to above, as well as through publication of information regarding adverse events on the DAEN and the COVID-19 weekly safety reports. The recent changes to the release of the DAEN-level data to the public serves to further benefit the public interest in this information.

***The TGA's suggested revised scope***

59. Other matters that may be relevant in deciding if a practical refusal reason exists include whether an applicant has cooperated in framing a request to reduce the processing workload (see paragraph [3.117] of the FOI Guidelines).

60. As mentioned in the background, the TGA FOI team emailed to advise you, whilst noting that they could not pre-empt my decision on internal review, that I had indicated a preliminary view that your request remained too voluminous to process. The TGA FOI team therefore suggested the following scope to you:

> *"the written components of the three studies in relation to histopathology/microscopic evaluation of gonads (ovaries/testes) of vaccinated animals in relation to Pfizer and AstraZeneca COVID-19 vaccines, excluding personal information, appendices, annexures and raw data".*

61. However, you did not agree to the TGA's suggested scope and chose to proceed with the internal review. The TGA's suggested scope was proposed on the basis that your revised FOI request remained too voluminous to process.

62. The TGA's technical experts have already been substantially diverted from their usual functions to consider your FOI request. By not agreeing to further narrow the scope of your request, I am of the view that the TGA has exceeded its obligations under the FOI Act to assist you. I am satisfied that the work involved in continuing to process this request would be an unreasonable diversion of the TGA's resources.

63. I reiterate the TGA's suggestion to you that you submit a new FOI request for the following documents to reduce the three studies from 3,667 pages to approximately 210 pages:

> *"the written components of the three studies in relation to histopathology/microscopic evaluation of gonads (ovaries/testes) of vaccinated animals in relation to Pfizer and AstraZeneca COVID-19 vaccines, excluding personal information, appendices, annexures and raw data".*

64. Please note, however, that the release of any documents will still be subject to the views of the relevant third parties (in particular, consultation with Pfizer and AstraZeneca will be required), and information that is exempt under the FOI Act will need to be redacted.

**Review and Complaint Rights**

65. If you are not satisfied with this decision, you are entitled to seek review by the Office of the Australian Information Commissioner (OAIC). A statement of your review and complaint rights is available on the OAIC's website, under the heading Reviews and Complaints – Information Commissioner Review:

    https://www.oaic.gov.au/freedom-of-information/reviews-and-complaints/information-commissioner-review/

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

Yours sincerely,

*Authorised and electronically signed by*

Dr Jane Cook
First Assistant Secretary
Medicines Regulation Division
Therapeutic Goods Administration
27 September 2021


**Freedom of Information Act 1982**

**24 Power to refuse request—diversion of resources etc.**

(1) If an agency or Minister is satisfied, when dealing with a request for a document, that a practical refusal reason exists in relation to the request (see section 24AA), the agency or Minister:
   (a) must undertake a request consultation process (see section 24AB); and
   (b) if, after the request consultation process, the agency or Minister is satisfied that the practical refusal reason still exists—the agency or Minister may refuse to give access to the document in accordance with the request.

(2) For the purposes of this section, the agency or Minister may treat 2 or more requests as a single request if the agency or Minister is satisfied that:
   (a) the requests relate to the same document or documents; or
   (b) the requests relate to documents, the subject matter of which is substantially the same.

**24AA When does a *practical refusal reason* exist?**

(1) For the purposes of section 24, a ***practical refusal reason*** exists in relation to a request for a document if either (or both) of the following applies:
   (a) the work involved in processing the request:
      (i) in the case of an agency—would substantially and unreasonably divert the resources of the agency from its other operations; or
      (ii) in the case of a Minister—would substantially and unreasonably interfere with the performance of the Minister's functions;
   (b) the request does not satisfy the requirement in paragraph 15(2)(b) (identification of documents).

(2) Subject to subsection (3), but without limiting the matters to which the agency or Minister may have regard, in deciding whether a practical refusal reason exists, the agency or Minister must have regard to the resources that would have to be used for the following:
   (a) identifying, locating or collating the documents within the filing system of the agency, or the office of the Minister;
   (b) deciding whether to grant, refuse or defer access to a document to which the request relates, or to grant access to an edited copy of such a document, including resources that would have to be used for:
      (i) examining the document; or
      (ii) consulting with any person or body in relation to the request;
   (c) making a copy, or an edited copy, of the document;
   (d) notifying any interim or final decision on the request.

(3) In deciding whether a practical refusal reason exists, an agency or Minister must not have regard to:
  (a) any reasons that the applicant gives for requesting access; or
  (b) the agency's or Minister's belief as to what the applicant's reasons are for requesting access; or
  (c) any maximum amount, specified in the regulations, payable as a charge for processing a request of that kind.

**24AB What is a *request consultation process*?**

*Scope*

(1) This section sets out what is a ***request consultation process*** for the purposes of section 24.

*Requirement to notify*

(2) The agency or Minister must give the applicant a written notice stating the following:
  (a) an intention to refuse access to a document in accordance with a request;
  (b) the practical refusal reason;
  (c) the name of an officer of the agency or member of staff of the Minister (the ***contact person***) with whom the applicant may consult during a period;
  (d) details of how the applicant may contact the contact person;
  (e) that the period (the ***consultation period***) during which the applicant may consult with the contact person is 14 days after the day the applicant is given the notice.

*Assistance to revise request*

(3) If the applicant contacts the contact person during the consultation period in accordance with the notice, the agency or Minister must take reasonable steps to assist the applicant to revise the request so that the practical refusal reason no longer exists.

(4) For the purposes of subsection (3), ***reasonable steps*** includes the following:
  (a) giving the applicant a reasonable opportunity to consult with the contact person;
  (b) providing the applicant with any information that would assist the applicant to revise the request.

*Extension of consultation period*

(5) The contact person may, with the applicant's agreement, extend the consultation period by written notice to the applicant.

*Outcome of request consultation process*

(6) The applicant must, before the end of the consultation period, do one of the following, by written notice to the agency or Minister:
  (a) withdraw the request;
  (b) make a revised request;
  (c) indicate that the applicant does not wish to revise the request.

(7) The request is taken to have been withdrawn under subsection (6) at the end of the consultation period if:

(a) the applicant does not consult the contact person during the consultation period in accordance with the notice; or

(b) the applicant does not do one of the things mentioned in subsection (6) before the end of the consultation period.

*Consultation period to be disregarded in calculating processing period*

(8) The period starting on the day an applicant is given a notice under subsection (2) and ending on the day the applicant does one of the things mentioned in paragraph (6)(b) or (c) is to be disregarded in working out the 30 day period mentioned in paragraph 15(5)(b).

Note: Paragraph 15(5)(b) requires that an agency or Minister take all reasonable steps to notify an applicant of a decision on the applicant's request within 30 days after the request is made.

*No more than one request consultation process required*

(9) To avoid doubt, this section only obliges the agency or Minister to undertake a request consultation process once for any particular request.