Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-3020031

[redacted]

FREEDOM OF INFORMATION REQUEST FOI 2565
Notice of Decision

1. I refer to your request dated 29 July 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) in which you sought access to 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."

2. On 21 August 2021, you revised the scope of your request to be for the following documents:

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

Decision Maker

3. I am the Therapeutic Goods Administration (**TGA**) officer authorised to make a decision on your request under the FOI Act.

Decision

4. I am notifying you of my decision under the FOI Act to refuse access to the documents that are the subject of your request.

5. I am satisfied that, following a request consultation process undertaken in accordance with section 24AB of the FOI Act, a 'practical refusal reason' exists within the meaning of paragraph 24AA(1)(a)(i) of the FOI Act.

6. The reason for practical refusal is that the work involved in processing your request would substantially and unreasonably divert the resources of the TGA from its other operations.

7. The reasons for my decision are set out in further detail below.

Background

8. On 29 July 2021, you submitted the above FOI request.

9. On 11 August 2021, the TGA advised you of the intention to refuse to give access to documents within the scope of your request. As required by paragraph 24(1)(a) of the FOI Act, a request consultation process commenced in accordance with section 24AB of the FOI Act, to provide you with the opportunity to revise the scope of your request so that a practical refusal reason would no longer exist.

10. Specifically, you were advised that it was likely that your request would, among other things, create an unreasonable diversion of the TGA's resources because it involved the review and consideration of 11 documents containing a total of 5,708 pages. The practical refusal reasons also indicated that:
    - the documents include the sponsors' clinical data and studies that are not public information, that is likely to have a commercial value to the sponsors that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.
    - the volume of commercially valuable information contained in the documents, which may make the documents exempt from release and would otherwise further compound the amount of third-party consultation required.
    - in particular, the documents requested include unpublished toxicology studies. Therefore, the preparation of these documents for release would require TGA officers to carefully review 5,708 pages for commercially sensitive information and make any appropriate redactions, in consultation with the third parties.
    - that advice on the data and sensitivity of the information in these documents would need to be provided by specialised technical staff at the TGA, including senior clinical medical officers, nurses, pharmacists and scientists, a majority of whom are presently engaged in analysis of adverse event data and investigation of safety issues relating to COVID-19 vaccines.
    - the assumption that a substantial number of those documents may be capable of being made available (even if in edited form with exempt material redacted), the time taken to appropriately edit each document and to make copies, particularly considering the large number of pages contained in the documents.
    - the fact that any decision letter would need to list each document in an attachment setting out the outcome of the consideration of whether exemptions apply.
    - the need to prepare third party decision letters and associated schedules, should any third-party object to the proposed release of their information.

11. The TGA also provided you with the publicly available information in relation to the developmental and reproductive toxicity studies and other publicly available resources to support the safety and efficacy of COVID-19 vaccines used in Australia, including the link to the TGA's disclosure log with reference to the key Pfizer documents considered by the delegate for the provisional approval of the COVID-19 vaccine, including the Investigator's Brochure.

12. You were invited to withdraw your request, refine the scope of your request or indicate that you did not wish to revise your request.

13. On 21 August 2021, you responded to the TGA as follows:

Taking into account what is publicly available from other FOI requests, I have revised my request as follows:

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

I provide the following further comments in response to the points raised in your letter.

Microscopic evaluation of reproductive tissue referred to in multiple places but not included in the publicly available FOI documents:

In relation to the publicly available FOI documents accessible on the TGA website, histology/histopathology in relation to reproductive organs is not available in these documents although it is referred to as having been done. However, the histopathology of other organs is available in these documents.

"Pre-Submission Meeting Briefing Document COVID-19 Vaccine (BNT162, PF-07302048)" – 18 September 2020 (available in "FOI 2389 document 3-1"):

- *Section 4.3.4 of this pre-submission document states "macroscopic and microscopic evaluation of male and female reproductive tissues were included in the GLP repeat-dose toxicity study testing … BNT162b2, and BNT162c1 in rat (Section 4.3.1)".*
- *However, section 4.3.1 does not contain any description of macroscopic or microscopic evaluation of male and female reproductive tissues. Table 4 in section 4.3.1, titled "Outcomes for Parameters Assessed in the Repeat-Dose Toxicity Study (Study No. 38166)" contains a row for "histopathology" and refers to injection sites, lymph nodes, bone marrow, spleen and liver, but does not include any description of reproductive tissue.*

"Investigator's Brochure" - 12 August 2020 (available in "FOI 2389 document 3-1"):

- *Section 5.3.1.15 states "macroscopic and microscopic evaluation of male and female reproductive tissues were included in the GLP repeat-dose toxicity study testing BNT162a1, BNT162b1, BNT162b2, and BNT162c1 in rat (Section 5.3.1)".*
- *However, section 5.3.1 does not contain any description of macroscopic or microscopic evaluation of male and female reproductive tissues. Table 9 in section 5.3.1, titled "Outcomes for parameters assessed in the repeat-dose toxicity study (Study No. 38166)" contains a row for "histopathology" and refers to injection sites, lymph nodes, bone marrow, spleen and liver, but does not include any description of reproductive tissue.*

As indicated in your letter, Pfizer has published developmental and reproductive toxicity study results: see at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8163337/. I have reviewed this study but it contains no reproductive tissue (ovaries/testes) histopathology/microscopic evaluation. The article states at page 33 that "the lack of female fertility effects is consistent with the lack of microscopic effects in female reproductive organs in non-pregnant rats administered BNT162b2 in prior general toxicology studies (data no shown)". It is because that data is not shown that as a clinician working in reproductive health I have made the present FOI request.

Response to practical reasons for refusal listed in your letter (my responses are in the right hand column):

"the estimated volume of documents involved, and the work involved in processing 11 documents containing a total of 5,708 pages"	*As mentioned above, histopathology results for other organs available in the pre-submission briefing document and Investigator's Brochure in relation to Pfizer take up one row in the relevant table of results (and accompany text regarding histopathology in the Investigator's Brochure is less than one page long).* *Therefore, I anticipate histopathology in relation to the gonads (ovaries/testes) of vaccinated rats regarding Pfizer and Astra Zeneca would be of a similar/smaller length (ie a few pages).*
"the documents include the sponsors clinical data and studies that are not publicly available and that are likely to have a commercial value to the sponsor that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed."	*If histopathology of other organs is publicly available I am not sure why the histopathology of the reproductive organs cannot be made publicly available.*
"the volume of commercially valuable information contained in the documents, which may make the documents exempt from release and would otherwise further compound the amount of third party consultation required"	*See my answers above.*
"in particular, the documents requested include unpublished clinical studies which are currently undergoing evaluation. Therefore, the preparation of these documents for release would require TGA officers to carefully review all 5,708 pages for commercially sensitive information and make any appropriate redactions, in consultation with the third parties. In this respect, I consider it significant that the data is not publicly available."	*The documents requested <u>do not</u> contain clinical studies. What I am requesting is pre-clinical data (animal data).* *And as above, I am not sure why histopathology of reproductive tissue should be any different in relation to commercial sensitivity than histopathology of other organs.*
"that advice on the data and sensitivity of the information in these documents would need to be provided by specialised technical staff at the TGA, including senior clinical medical officers, nurses, pharmacists and scientists, a majority of whom are presently engaged in analysis of adverse event data and investigation of safety issues relating to COVID-19 vaccines"	*Again, if all other histopathology is available I am not sure why histopathology of reproductive tissue poses any difficulty. I am a reproductive clinician answering patient questions regarding COVID-19 vaccination.*
"the assumption that a substantial number of those documents may be capable of being made available (even if in edited form with exempt material redacted), the time taken to appropriately edit each document and to make copies, particularly considering the large number of pages contained in the documents."	*Again, given the minimal amount of material involved (evidenced by other organ histopathology reports presented), I am hopeful the time required to prepare material for release would not be substantial.*

"the fact that any decision letter would need to list each document in an attachment setting out the outcome of the consideration of whether exemptions apply."	*Again, as I would anticipate a minimal amount of material (based on the amount of material in relation to histopathology of other organs), I wouldn't anticipate this document would be long.*
"the need to prepare third party decision letters and associated schedules, should any third party object to the proposed release of their information"	*I have no further comment in relation to this point."*

Material considered in Decision-Making

14. In making my decision, I have had regard to:

- the terms of your FOI request and subsequent correspondence between you and the TGA;
- the TGA's assessment of the time and resources that would be required to process your request;
- documents falling within the scope of your request, including the time involved to consult with the third parties;
- relevant provisions of the FOI Act, including sections 24, 24AA and 24AB. In particular, the mandatory considerations in section 24AA(2) of the FOI Act regarding whether a practical refusal reason exists, including the resources that would be required to:
    - identify, locate or collate documents falling within the scope of the FOI request;
    - examine the relevant documents and consult with any person or body in relation to the request;
    - make copies or edited copies of the documents; and
    - notify you of the final decision.
- the guidelines issued by the Information Commissioner under subsection 93A(1) of the FOI Act that I am required to have regard to under subsection 93A(2) of the FOI Act; and
- information from the relevant area of the TGA concerning the resources required to comply with your request, and the effect of the same on the TGA's operations, including the staffing resources available to the TGA and the extent to which processing this request would divert resources from other matters important to the TGA's functions of protecting public health and safety.

Relevant provisions of the FOI Act

15. Subsection 24AA(1) of the FOI Act defines when a 'practical refusal reason' will exist in relation to a request. A copy of the relevant sections of the FOI Act (sections 24, 24AA and 24AB) are available at **Attachment A**.

16. A practical refusal reason exists if the work involved in processing the request would substantially and unreasonably divert the resources of the agency form its other operations (see subparagraph 24(1)(a)(i) of the FOI Act).

17. Subsection 24AA(2) of the FOI Act sets out the matters to which I must have regard in deciding whether a practical refusal reason exists. Specifically, it states:

> *(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) modifying any interim or final decision on the request.*

18. Subsection 24AA(3) of the FOI Act sets out the matters to which I must not have regard to and so I confirm that I have not had regard to any of those matters in coming to my decision.

Reasons for Decision

Request remains too voluminous to process

19. You have revised the scope of your request to be for the following documents, *"histopathology/microscopic evaluation of gonads (ovaries/testes) of vaccinated animals in relation to Pfizer and AstraZeneca COVID-19 vaccines"* (**the Revised Scope Request**). Nevertheless, the TGA maintains the view that your FOI request remains too voluminous to process.

20. There are three toxicology studies falling with the Revised Scope Request. There are two studies for Pfizer and one study for AstraZeneca that consider the histopathology and microscopic evaluation of animals in relation to the COVID-19 vaccines.

21. The two Pfizer studies are 603 pages and 2,237 pages, respectively, and the AstraZeneca study is 827 pages. The total number of pages for the three studies is 3,667 pages. The subject matter of the Revised Scope Request is intermingled throughout the studies and so it is not possible to consider only the pages that relate to the histopathology and microscopic evaluation of gonads. Therefore, the TGA would be required to determine whether to refuse or grant access to an edited copy of each of the 3,667 pages of the three documents.

22. I have taken into account the time required to determine whether to refuse or grant access to an edited copy of the three documents containing 3,667 pages, edit and make copies of the documents and prepare the decision letter and any third party decision letters and schedules required. The number of pages contained in the three toxicology studies makes the Revised Scope Request too voluminous to process.

23. Further, the documents are likely to require numerous redactions as the documents are unpublished studies that contain information that is commercially sensitive and valuable, for example, detailed data and results of the toxicology studies. In this respect, I consider it significant that the data is not publicly available.

24. I do not agree with your response to the request consultation letter dated 21 August 2021 (set out in the background above). It is not correct that the histopathology in relation to reproductive tissues is contained within 'a couple of pages'. As mentioned above, it is not possible to extract those pages from the studies (as the information is intermingled throughout the documents).

25. It is also not appropriate to compare the information in the Investigator's Brochure to surmise what is contained in the studies. Whilst the Investigator's Brochure summarises the toxicology studies, it does not contain all of the information on those studies. Furthermore, the Investigator's Brochure was made publicly available under the FOI Act in response to an FOI request, and the TGA considered each page of the Investigator's Brochure to determine whether the information had commercial value and had to consult the third party in relation to the document.

26. I consider the nature of the information in the three studies relevant, in that it concerns specific processes, materials, methods and designs used to carry out the toxicology studies and comprehensive and detailed data relating to the statistical analysis and results. Accordingly, I would be obliged to consult Pfizer and AstraZeneca and obtain any submissions they may wish to make regarding the release of the documents.

27. A range of the TGA's important public health functions would also be adversely affected by the continued processing of this request in its current form, in particular, technical experts from the Scientific Evaluation Branch and Prescription Medicines Authorisation Branch would be diverted from considering applications for approval/variation of COVID19 vaccines in order to advise the TGA FOI team on the release of the documents falling within the scope of this FOI request.

28. While undertaking this FOI work, these staff members would not be performing their ordinary regulatory functions, which for more than twelve [12] months now has significantly increased due to the effect of the COVID-19 pandemic. This could cause delays to the TGA's role of regulating therapeutic goods under the *Therapeutic Goods Act 1989*.

29. I further note that resources to process your request would also need to be diverted from a range of other business support areas, including the Regulatory Legal Services Branch, and the Reporting & Collaboration Services Section (being the section responsible for processing FOI requests).

30. 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*.

Review and complaint rights

31. 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/

32. Should you have any enquiries concerning this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely,

Michael Wiseman
Assistant Secretary
Scientific Evaluation Branch
Therapeutic Goods Administration
26 August 2021