Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-3367690

Mr Tim Murphy
By Email: foi+request-8025-6215611a@righttoknow.org.au

Dear Mr Murphy,

FREEDOM OF INFORMATION REQUEST FOI 3277
Notice of Decision

1. I refer to your request dated 27 October 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) for access to the following documents:

   "1. Documents pertaining to trials done on the safety of the Covid19 vaccines on pregnant woman.

   2. Documents on the affects of fertility in prenatal woman"

Decision maker

2. I am the TGA officer authorised to make a decision on your request under the FOI Act.

Request too voluminous to process

3. The TGA has now undertaken a preliminary search and retrieval for the documents coming within the scope of your request. As a result, TGA officers have indicated that your request includes documents that are too voluminous to process, and otherwise, the information you have requested is publicly available.

4. In relation to item 1 of your request, your request includes a number of monthly safety reports and Periodic Safety Update Reports received by the TGA from vaccine sponsors. These reports contain, on average, approximately 8,000 pages, with some reports containing in excess of 13,000 pages.

5. As this item of your request was found to be too voluminous to process, the TGA has not continued processing the remainder of your request. However, the relevant line areas have indicated that a significant proportion of the safety reports are likely to be relevant to your request. The TGA currently holds 48 reports which may be relevant, containing approximately 8,000 pages on average.

6. Further, a number of additional documents, additional to the safety reports provided by the sponsor, are likely to be relevant to item 1 of your request. There are further technical areas within the TGA where searches have not been completed which are likely to hold additional relevant documents. Therefore, the total number of relevant documents (and pages contained within such documents) remain too voluminous to process.

7. As the items of your request mentioned above have been found to be too voluminous to process, the TGA has not continued processing item 2 of your request.

Requirement to undertake a request consultation process

8. Under paragraph 24(1)(a) of the FOI Act, I, as a decision maker must consult you if I am satisfied that a "practical refusal reason" exists in relation to your request. A practical refusal reason exists if the work involved in processing the request would substantially and unreasonably divert the resources of the TGA from its other operations. A copy of the sections of the FOI Act that set out the consultation process (sections 24, 24AA and 24AB) is at **Attachment A**.

9. In deciding whether the processing of your request would involve a substantial and unreasonable diversion of resources such that a practical refusal reason exists, I am required under section 24AA(2) of the FOI Act to consider the resources that would have to be used in the following activities:
   - identifying, locating and collating the documents;
   - deciding whether to grant or refuse access to each document and/or to provide an edited copy which would include examining each document and consulting with any person (including those that I would be required to consult under the FOI Act);
   - making a copy or edited copy of each document; and
   - notifying any interim or final decision on the request (including to any third party consulted in the event that a decision is made to give access to the documents despite the objections of the relevant third party).

10. In coming to a view that a practical refusal reason exists in relation to your request, I have had regard to the following:
    - the estimated volume of documents involved, and the work involved in processing them. There are likely to be a significant number of further documents captured by the scope of item 1 of your request, including other safety reports which contain an average of 8,000 pages each.
    - this figure also does not include documents captured by the scope of item 2 of your request.
    - each of these documents are likely to include commercially valuable information and business information of vaccine sponsors, in relation to which, consideration would need to be given about whether an exemption should be claimed and whether consultation with the relevant third party is required, and, if so, preparation of schedules for the third party detailing all relevant documents.
    - the number of affected third parties. There are likely to be at least four relevant third parties, including the sponsors for each COVID-19 vaccine provisionally approved in Australia.
    - as you would appreciate, the TGA would need to write to each third party individually, attach copies of their documents, and consider the responses provided and any requested redactions. I would then need to make a decision on these documents, considering these submissions. In addition, if any of the third parties objected to release of documents and I disagreed with them, then I would need to provide them with a decision.
    - 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 (i.e. senior medical officers, nurses, pharmacists and scientists), a majority of whom are presently engaged in ongoing analysis and monitoring of the safety and efficacy of 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.
- 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.

11. I consider that the number of pages contained within the relevant documents falling within the scope of your request, the fact that much of the information is commercially valuable information, combined with the number of third parties, and the necessary consequential work associated with considering whether the documents may be lawfully disclosed, would have a substantial effect on the operations of the TGA.

12. I find that the work involved in processing this request would be an unreasonable diversion of the TGA's resources, including TGA officers engaged in safety monitoring of medicines and vaccines. As to the critical work that these officers perform, I note that analysis and investigation of medicine and vaccine safety issues, and associated regulatory actions, are of significant public health impact. As you would appreciate, if these officers are required to consider large FOI requests, this diverts their time and attention from undertaking their primary role as evaluators.

13. In addition, the administrative team providing critical support to the TGA's evaluators and the other safety monitoring business of the TGA and the FOI team are also currently dealing with a high volume of COVID-19 related FOI requests. Processing your request would tie up resources of those teams that would otherwise be involved in supporting evaluators, the broader operations of the TGA's medicines safety monitoring business and processing other FOI requests. 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).

14. I also note that there are likely to be significant charges imposed on you for processing your request (as calculated in accordance with the *Schedule to the Freedom of Information (Charges) Regulations 2019*) based on the number of documents, the number of pages contained within the documents, and multiple third parties.

Guidance on accessing the TGA's publicly available information

15. I note that paragraph 3.117 of the FOI Guidelines indicates another matter I may take into account in deciding whether a practical refusal reason exists is whether there is a significant public interest in the documents requested and what information is published. I consider that there is a public interest in evidence supporting the safety and efficacy of COVID-19 vaccines that will be used in Australia.

16. To a very large degree, that interest has already been met by publication of the regulatory documents for COVID-19 vaccines and other relevant information.

17. The TGA has published a range of regulatory documents relating to the provisional approval of each COVID-19 vaccine, which provide detailed information regarding the evaluation process, the data that were considered, and any adverse effects. These include the Australian Public Assessment Report (**AusPAR**), the Product

Information (**PI**) and the Consumer Medicine Information (**CMI**), and they are available at: www.tga.gov.au/covid-19-vaccines.

18. The PI is the key source of information for health professionals as it provides a summary of the scientific information relevant to the safe and effective use of a prescription medicine, including vaccines. The PI is approved by the TGA, and sponsors must submit an application to the TGA to make any change to the PI. The PI includes information about the structure and results of clinical trials, as well as any adverse events observed from post-market surveillance. The TGA works with COVID-19 vaccine sponsors to ensure the PI remains up to date and can mandate updates to the safety information included in the PI.

19. The public interest in evidence supporting the safety and efficacy of COVID-19 vaccines is also met through the publication of a weekly safety report which provides the outcomes of our ongoing monitoring and safety investigations. All weekly safety reports remain available on the TGA website at: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report.

20. Further, I wish to advise you that there is no evidence, credible scientific theory, or known biologically plausible mechanism that COVID-19 vaccines cause infertility in humans. There is also no evidence that antibodies formed from COVID-19 vaccination cause any problems with pregnancy, including the development of the placenta. One disproven theory that COVID-19 vaccines cause infertility is based on the idea that the spike protein of SARS-CoV-2 and the Syncytin-1 protein (which help placenta development) are the same. They are not.

21. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and ATAGI have released a joint statement recommending that:

    - Pregnant women are a priority group for COVID-19 vaccination and should be routinely offered the Pfizer vaccine (Comirnaty) or Spikevax (Moderna) at any stage of pregnancy.
    - Pfizer (Comirnaty) and Spikevax (Moderna) are mRNA vaccines
    - Women who are trying to become pregnant do not need to delay vaccination or avoid becoming pregnant after vaccination.
    - There is no evidence of increased risk of miscarriage or teratogenic risk with mRNA or viral vector vaccines.
    - Global evidence has shown that the Pfizer and Moderna vaccines are safe for pregnant women.
    - Pregnant women have a higher risk of severe illness from COVID-19.
    - Their babies also have a higher risk of being born prematurely.
    - COVID-19 vaccination may provide indirect protection to babies by transferring antibodies through the placenta (for pregnant women) or through breastmilk (for breastfeeding women).

    The full statement is available at: https://ranzcog.edu.au/statements-guidelines/covid-19-statement/covid-19-vaccination-information

22. A number of studies regarding the effect of COVID-19 vaccines on fertility and pregnancy are also available in the public domain. For example, the following animal studies for Pfizer and Moderna vaccines have not shown any negative effects on fertility or pregnancy:

    - Bowman CJ, Bouressam M, Campion SN, et al. "Lack of effects on female fertility and prenatal and postnatal offspring development in rats with BNT162b2, a mRNA-based COVID-19 vaccine." *Reproductive Toxicology* 2021, available at:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8163337/.

- United States Food and Drug Administration. Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum. Accessed August 10, 2021. https://www.fda.gov/media/144673/download

23. In relation to research on COVID-19 vaccines and male fertility, the following study is also available in the public domain: 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.

24. The public interest is also met by the publication of several relevant documents on the TGA FOI disclosure log in response to previous FOI requests. You may particularly wish to consider FOI-2289 (Document 1). This Pfizer study is a combined fertility and developmental study of BNT151b1, BNT162b2 and BNT162b3 by Intramuscular Administration in the Wistar Rat.

25. I also wish to advise you that details of current clinical trials, including trials conducted on the safety of COVID-19 in pregnant women, are available in the public domain. You can search for information about clinical trials using COVID-19 vaccines by searching clinical trial registries. These registries include detailed information about the status of clinical trials. More information is available at: https://www.australianclinicaltrials.gov.au/clinical-trial-registries. Key clinical trial registries containing information on major clinical trials of the COVID-19 vaccine are available at:
    - https://www.clinicaltrialsregister.eu/ctr-search/search
    - https://clinicaltrials.gov/ct2/results?cond=COVID-19

26. Further information is also publicly available at https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/is-it-true/is-it-true-do-covid-19-vaccines-cause-infertility. More information can also be found in the COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy, which is regularly updated as more information and new vaccines become available.

27. I consider that insofar as any interest is served by the release of the documents in question, the public interest has already been met through the publication of the supporting regulatory documents, the COVID-19 weekly safety reports, and publicly available clinical information.

28. I find that the balance of interests does not favour the expenditure of considerable resources by the TGA. The above diversion of TGA resources would, in my view, be substantial, and is likely to cause serious delays to, and potentially compromise, the TGA's performance of its regulatory functions under the *Therapeutic Goods Act 1989*. Having regard to the importance of the prompt and proper performance of the TGA's regulatory functions, I consider that this diversion of resources would be unreasonable in the circumstances.

Notification of request consultation process

29. I am notifying you of my intention to refuse to give access to the documents that come within the scope of your request.

30. Before deciding to refuse access to documents, I am required under paragraph 24(1)(a) of the FOI Act to undertake a request consultation process in

accordance with section 24AB of the FOI Act and provide you with the opportunity to refine the scope of your request.

31. Accordingly, you are now afforded fourteen (14) calendar days from your receipt of this letter in which to contact the TGA to discuss a revision of the scope of your request.

32. Before the end of the 14-day consultation period, you must do one of the following:
    - withdraw your request;
    - make a revised request; or
    - indicate that you do not wish to revise your request.

33. If you have not contacted the TGA within 14 days of receiving this letter to do one of the above or consulted the TGA to discuss revising the scope of this request, your request is taken to have been withdrawn.

34. If you wish to refine the scope of your request, you may contact the TGA FOI team on (02) 6289 4630 or at TGA.FOI@tga.gov.au.

35. Please note that if you indicate that you do not wish to revise your request or revise your request in such a way that I am still of the view that processing it would substantially and unreasonably divert TGA resources from other operations, I may refuse your request under paragraph 24(1)(b) of the FOI Act.

Yours sincerely,

Authorised and electronically signed by

Olivia Cocks
Director
Pharmacovigilance Branch
Therapeutic Goods Administration
24 November 2021