Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-2842986

[redacted]

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FREEDOM OF INFORMATION REQUEST FOI 2451
Request Consultation Process

1. I refer to your request dated 15 June 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) in which you sought access to the following documents:

   "1. All documents that the trials or studies that have been done with the COVID injections and pregnant women.
   2. All documents which show that the COVID injections are safe for pregnant women.
   3. All documents which show the trials or studies detailing how the COVID injections affect fertility.
   4. All documents which show the trials that have been done with the Covid Injections and people 70 and over.
   5. All documents that show the TGA advised all Australians that the Covid Injections are an experiment and not a true Vaccine."

Decision Maker

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

No documents for items 1 or 5 of your request

3. At the outset, I note that there are no documents for items 1 or 5 of your request. Some information relating to items 2, 3 and 4 are available in the public domain. However, documents held by the TGA (that are not publicly available) in relation to items 2 and 3 of your request are otherwise too voluminous to process.

4. In relation to item 1 of your request, the TGA does not hold documents of trials or studies of COVID injections in pregnant women. When the TGA provisionally registered the Pfizer and AstraZeneca COVID-19 vaccines early this year, there was limited evidence confirming the safety of COVID-19 vaccines during pregnancy. This is because pregnant women were not included in the first clinical trials for the COVID-19 vaccines. At that time, the TGA advised that pregnant women should discuss the decision to use these vaccines with their healthcare professionals to determine whether the benefits of vaccination outweighed any potential risks for the mother and her unborn child.

5. Ongoing studies to demonstrate the safety and efficacy of these vaccines have since shown that the Pfizer and Moderna mRNA vaccines are safe for pregnant and breastfeeding women. There have been a number of recent studies published in some of the world's top medical journals, including:
   - 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

6. On 9 June 2021, the Australian Technical Advisory Group on Immunisation (ATAGI) and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) released a joint statement recommending that pregnant women should be routinely offered the Pfizer Comirnaty mRNA vaccine at any stage of pregnancy. The joint statement is available here: https://www.health.gov.au/news/joint-statement-between-ranzcog-and-atagi-about-covid-19-vaccination-for-pregnant-women

7. More information can be found in the COVID-19 vaccination decision guide for women who are pregnant, breastfeeding or planning pregnancy. The guide is regularly updated as more information and new vaccines become available. The guide is available here: 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

8. In relation to item 5 of your request, the TGA does not hold any documents that *"show that the TGA advised all Australians that the COVID injections are an experiment and not a true vaccine".*

Publicly available information regarding items 2, 3 and 4 of your request

9. Some information relating to items 2, 3 and 4 are available in the public domain. However, documents held by the TGA (that are not publicly available) in relation to items 2 and 3 of your request are otherwise too voluminous to process.

10. In relation to the documents in the public domain for items 2 and 3, you may wish to view the TGA's Disclosure Log at www.tga.gov.au/foi-disclosure-log and the documents released in response to FOI 2289 (namely, FOI document 1).

11. In relation to item 4 of your request, you may wish to view the TGA's disclosure log and the documents released in response to FOI 2183 (in particular, FOI documents 3, 5 and 9).

12. There is also further information on the studies available in the public domain. For example, further information on the Pfizer and AstraZeneca studies is available at the Lancet website: https://ars.els-cdn.com/content/image/1-s2.0-S0140673620326611-mmc2.pdf

13. You may also wish to consider the publicly available material at the following links:
    - due to the urgent nature of the COVID-19 pandemic, COVID-19 vaccines have received a provisional registration status and further information about this can be found here: https://www.tga.gov.au/provisional-approval-pathway-prescription-medicines
    - information relating to full registration of a product can be found here: https://www.tga.gov.au/prescription-medicines-registration-process
    - further information on the COVID-19 vaccines is available here:
        - www.tga.gov.au/covid-19-vaccines
        - www.health.gov.au/initiatives-and-programs/covid-19-vaccines?utm_source=health.gov.au&utm_medium=redirect&utm_campaign=digital_transformation&utm_content=covid19-vaccines
        - www.tga.gov.au/batch-release-assessment-covid-19-vaccines
        - https://www.tga.gov.au/reporting-adverse-events

- https://www.tga.gov.au/covid-19-vaccine-pfizer-australia-comirnaty-bnt162b2-mrna
- https://www.tga.gov.au/covid-19-vaccine-astrazeneca-chadox1-s
- https://www.tga.gov.au/database-adverse-event-notifications-daen

14. You may also wish to consider the information in the supporting regulatory documents, including the Product Information (PI). 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 on adverse events which were observed in clinical trials, as well as those 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.

15. The PIs are publicly available here: https://www.tga.gov.au/product-information-0. If you click "search PI documents" on this page, it will take you to a search bar where you can search for the COVID-19 vaccines and find the relevant PI.

Requirement to undertake a request consultation process

16. 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. As mentioned above, I am of the view that a practical refusal reason exists in relation to items 2 and 3 of your request.

17. A copy of the sections of the FOI Act that set out the consultation process (sections 24, 24AA and 24AB) is at **Attachment A**. 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).

18. In coming to a view that a practical refusal reason exists in relation to your request, I have had regard to the following:
    - the correspondence from you dated 15 June 2021, including the terms of your request.
    - the TGA's email to you dated 28 June 2021, where you were asked to confirm whether you were seeking access to personal information and duplicate documents. As you did not respond to this email, we have assumed that you are seeking access to personal information and duplicates.
    - the estimated volume of documents within scope of your request and the work involved in processing them. Namely, preliminary estimates from the relevant line areas of the TGA identified 14 documents containing more than 56,396 pages in relation to items 2 and 3 of your request.

- the fact that each of the documents is likely to contain business and/or personal information, 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. This is particularly relevant as the data from the sponsors includes the clinical data, manufacturing processes and formulation information for the vaccine that is non-public information 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.
- 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., toxicologists, pharmaceutical chemists and senior clinical medical officers), a majority of whom are presently engaged in consideration of at least one other application for registration of a COVID-19 vaccine as well as reasonably regular applications for variation of existing registrations 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.
- the need to prepare third party decision letters and associated schedules (noting that these documents related to three (3) different sponsors of the COVID19 vaccine), should any third party object to the proposed release of their information.

19. Taking into account these matters, I have prepared an estimate of charges in relation to your request. For that purpose, I have:
    - considered the time required to undertake the consultation process with the sponsors.
    - considered the time already taken to perform searches for potentially relevant documents.
    - estimated how long it might take to process the 14 documents containing approximately 56,396 pages. The estimate of charges calculator has calculated that the processing of this request could take at least 1357 hours.

20. I consider that the number of pages estimated to fall within the scope of your request combined with the fact that much of the information is commercially confidential information 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.

21. I also find, for the following reasons, that the work involved in processing this request would be an unreasonable diversion of the TGA's resources, including TGA's officers engaged in evaluation and assessment of prescription medicines, including vaccines. As to the critical work that these officers perform, I note that evaluation and assessment of applications for registration for vaccines and other prescription medicines are required to be finalised within strict statutory timeframes. 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.

22. In addition, the administrative team providing critical support to the TGA's evaluators and the other prescription medicine 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 engage resources of those teams that would otherwise be supporting evaluators, the broader operations of the TGA's prescription medicine business and processing other FOI requests. In this regard, the FOI Guidelines states that a relevant matter in deciding 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 (emphasis mine)** (see paragraph 3.117 of the FOI Guidelines).

23. The time to review the 14 documents in detail to determine whether any of the documents or parts of the documents could be characterised as exempt, and then redacting the material, would be a substantial and unreasonable diversion of the TGA's resources. Further, I estimate that the charges that may be imposed on you for processing your request (as calculated in accordance with the *Schedule to the Freedom of Information (Charges) Regulations 2019*, may, based on the number of hours, exceed $27,149.

24. 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. To a very large degree that information is in the supporting regulatory documents, including the PI, and the other information that is publicly available (see the links provided above). Therefore, I consider that insofar as any interest is served by the release of the documents in question, that interest has already been met through the publication of these documents.

25. I find that the balance of interests does not favour the expenditure of considerable resources by the TGA. I am satisfied that the diversion of resources to provide documents in response to your request is not reasonable.

Notification of request consultation process

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

27. 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.

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

29. 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.

30. You may wish to consider the following suggestion to revise the scope of your request (please note that this is a suggestion only and does not guarantee the practical refusal reason will no longer exist):
    a. wait until you have reviewed the links to the publicly available material to determine whether a further FOI request for documents is necessary (i.e. you may wish to make another FOI request once you have had an opportunity to review the material in the public domain, noting the information being included on the TGA's FOI disclosure log).

31. 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 its scope, your request is taken to have been withdrawn.

32. 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.

33. 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

Elizabeth Santolin
Director
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
14 July 2021