Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-3366920

Mr Michael Betts
By Email: foi+request-8064-eebf1f84@righttoknow.org.au

Dear Mr Betts,

FREEDOM OF INFORMATION REQUEST FOI 3346
Request Consultation Process

1. I refer to your request dated 4 November 2021 under the *Freedom of Information Act 1982* (**the FOI Act**) for access to the following documents:

   "I am requesting access to information under the Freedom of Information Act, such information being all documents that you hold in relation to the use of aborted fetus cell lines in the testing of COVID-19 vaccines."

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. In various stages of development and manufacturing, some COVID-19 vaccines may use material originally sourced from a human embryo.

4. For provisionally approved COVID-19 vaccines where this is the case, including VAXZEVRIA (AstraZeneca) and COVID-19 VACCINE JANSSEN (Janssen-Cilag), a corresponding statement is included the Australian Product Information (PI).

5. The TGA has now undertaken a preliminary search and retrieval for the documents considered to be within the scope of your request. As a result, TGA officers have indicated that your request includes documents that are too voluminous to process.

6. The TGA has taken a broad interpretation of the scope of your request and notes that your request is likely to include documents provided to the TGA by COVID-19 vaccine sponsors, including the AstraZeneca and Janssen-Cilag vaccines, as part of the vaccine provisional approval process. During a preliminary search, the relevant line area of the TGA identified at least 146 documents containing 43,479 pages that were provided by AstraZeneca alone as part of its application for provisional approval.

7. Further, a number of additional documents, beyond the provisional approval documents are likely to be relevant to your request. There are additional areas where searches have not been completed which are likely to have additional relevant documents and therefore the total number of relevant documents is likely to be significantly more voluminous than the 43,479 pages contained within the identified documents.

8. As the scope of your request has been found to be too voluminous to process, the TGA has not continued processing your request.

Requirement to undertake a request consultation process

9. 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**.

10. 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).

11. 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. For example, the identified documents provided by AstraZeneca that may be relevant to your request contain 43,479 pages. There are likely to be a significant number of further documents likely to be captured by the scope of your request, held by other technical areas of the TGA.
    - 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 is likely to be at least two relevant third parties, including the sponsors for each COVID-19 vaccine mentioned above, that sought provisional approval 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.

12. 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.

13. 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.

14. 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).

15. 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 third parties.

Guidance on accessing the TGA's publicly available information

16. 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.

17. 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.

18. 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.

19. 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. As stated above, if a vaccine's manufacture uses material sourced from a human embryo this is clearly stated in the PI.

20. 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. Further information about the provisional approval of COVID-19 vaccines and the provisional approval process is available on the TGA website.

21. 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.

22. 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 information.

23. 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

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

25. 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.

26. 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.

27. 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.

28. The current scope of your request is very broad in nature and does not enable the TGA to identify discrete documents falling within the scope of your request. You may wish to nominate a date range for your request, clarify whether you are seeking documents provided to the TGA from particular third parties or specify particular subject matter relating to foetal cell lines.

29. 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.

30. 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.

31. 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

Dr Grant Pegg
Assistant Secretary, Prescription Medicines Authorisation Branch
Medicines Regulation Division
Therapeutic Goods Administration
3 December 2021