Australian Government

Department of Health
Therapeutic Goods Administration

Alissa Pattrick

Email: foi+request-5356-757ea70f@righttoknow.org.au

Dear Ms Pattrick

FREEDOM OF INFORMATION REQUEST FOI 1109-1819
Request Consultation Process

I refer to your request dated 6 April 2019 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

> *"...Can I please have a copy of:*
>
> *- The double-blind placebo safety study and report which shows that the flu immunisation for Australia in 2019 is safe for human pregnant women at any stage of their pregnancy as is suggested on the national website below, which at the time of submission was last updated 27/03/19, https://beta.health.gov.au/services/flu-influenza-immunisation-service and reads "Flu immunisation is recommended every year for: ... pregnant women at any stage of pregnancy, for free under the NIP ..."*
>
> *- Any and all double blind placebo safety studies and reports which show that the recommended flu immunisation since the introduction of flu immunisations are safe for human pregnant women at any stage of their pregnancy as is suggested on the national website*
>
> *- Any study and report on the current or previous flu immunisation which was not funded by the manufacturer*
>
> *- Any complaints/feedback/correspondence to the TGA from licensed medical professionals regarding the short and long term health outcomes of their pregnant patients post flu immunisation.*
>
> *- Any internal discussion in relation to the above*
>
> *To assist the Department, I specifically exclude:*
>
> *- Duplicates of documents (I only require 1 copy of each document)*
>
> *Where possible, I would prefer that this information is provided in it's original format - that is to say, either in Microsoft Word or HTML (where received online or via email). I ask that you do not use PDFs wherever possible as it makes it difficult to read the information.*
>
> *Please deal with this request informally or in accordance with your Administrative Access scheme if practicable. If this isn't practical, please consider it a formal application under the Freedom of Information Act."*

Decision Maker

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

Requirement to undertake a request consultation process

The TGA has now undertaken a preliminary search and retrieval for documents coming within the scope of your request. As a result, TGA officers have indicated that there are approximately 405,000 relevant pages that would have to be processed for your request to be finalised.

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.**

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 entitled 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 document and the third party objects).

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 of 6 April 2019, including the terms of the FOI request;
- the estimated volume of documents involved and the work involved in processing them - preliminary estimates from the relevant line areas of the TGA identified approximately 7,409 documents containing more than 405,000 pages consisting of approximately:
    - 2,469 electronic files; and
    - 2,016 third parties.
- 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 higher than the estimate;
- the need to prepare a schedule detailing all relevant documents;
- the fact that each of those documents may 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 third parties is required and if so, preparation of schedules for the third party detailing all relevant documents;

- 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; and
- the need to prepare third party decision letters and associated schedules, should any third parties object to the proposed release of their information (noting the number of third parties required to be consulted).

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 2,016 potential third parties; and
- the time already taken to perform searches for potentially relevant documents and the additional time required to complete the remaining searches.

Based on my conclusion that the processing of your request could take approximately 32,795 hours, I consider your request to be an unreasonable diversion of the TGA's resources to process in its current form. 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) Regulations2009)*, may, based on the estimated number of hours, exceed $644,327.

Notification of request consultation process

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

I am satisfied that, because of the number of documents involved in your request, the number of third parties that would need to be consulted, and the number of hours involved in considering exemptions and making a decision on the documents as set out above, your request would substantially and unreasonably divert staff in regulatory areas of the TGA who would be required to review and consider the documents and any submissions provided by third parties on the documents, from the performance of their day-to-day functions.

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.

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. If you wish to refine the scope of your request you may contact the FOI Team on (02) 6232 8806 or at TGA.FOI@tga.gov.au.

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.

You may wish to consider the following suggestions to revise the scope of your FOI request (please note that these are suggestions only and do not guarantee the practical refusal reasons will no longer exist):

- include a date range for the relevant documents, for example , documents from 1 July 2017

- exclude duplicate documents, that is, where identical documents are retrieved from different areas
- exclude personal information
- request public case details of reports with a coded reaction that includes the System Order Class of 'Pregnancy, puerperium and perinatal conditions' or coded MedDRA terms related to exposure during pregnancy

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, your request is taken to have been withdrawn.

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

Mark McDonald
Senior Manager
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
17 May 2019