



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

Renee

**Email:** [foi+request-5424-4d2c16b6@righttoknow.org.au](mailto:foi+request-5424-4d2c16b6@righttoknow.org.au)

Dear Renee

**FREEDOM OF INFORMATION REQUEST FOI 1158-1819**  
**Request Consultation Process**

I refer to your request dated 20 May 2019 under the *Freedom of Information Act 1982* (the FOI Act) and subsequent correspondence from the TGA to you in which the scope of your request was clarified as being for access to the following documents:

*“For the purposes of the Freedom of Information Act, I seek access to a document which lists all vaccines available in Australia and where they are manufactured.”*

**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 21 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).

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 20 May 2019, including the terms of the FOI request, and subsequent correspondence from the TGA attempting to clarify the scope of your 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 21 relevant pages consisting of the need to consult at least 12 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 at least 12 third party decision letters and associated schedules, should any third parties object to the proposed release of their information.

Taking into account these matters, I have prepared an estimate of charges in relation to your request. For that purpose, I have:

- taken a conservative approach to attributing 1 relevant document per potential file, both electronic and hard copy;
- considered the time required to undertake the consultation process with the 12 potential third parties; and
- considered 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 in excess of 51 hours, I estimate that, calculated by reference to the charges set out in the Schedule to the *Freedom of Information (Charges) Regulations 1982*, the total charges that may be imposed on you for processing your request may exceed \$1,015.00. Accordingly, I consider your request to be an unreasonable diversion of the TGA's resources to process in its current form.

#### **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 third parties requiring consultation 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.

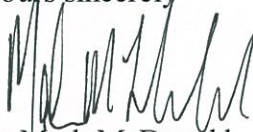
You may wish to consider the following suggestions to revise the scope of your FOI request (please note that these are suggestions only and do not guarantee the practical refusal reason/s will no longer exist):

- As previously advised on 24 May 2019, I recommend you search the Australian Register of Therapeutic Goods (ARTG) for the information you are seeking. You can find the ARTG here: <https://www.tga.gov.au/artg>. Here you will find publicly available information that does not need to be accessed under the FOI Act. Anyone can find all registered medicines, including vaccines, that are approved for supply in Australia. Noting however, not all registered medicines are necessarily being supplied regardless of approval;
- As previously advised on 24 May 2019 and 4 June 2019, you may wish to consider excluding '*... and where they are manufactured*' from the scope of your request. For vaccines, there are frequently multiple steps involved in the manufacture covering multiple sites and there remains a requirement to consult all manufacturers of each vaccine. As such, as your request relates to the personal, professional, business, commercial or financial affairs of third parties, pursuant to section 27 and 27A of the FOI Act, the TGA is required to consult with the affected third parties and provide them an opportunity to make submissions regarding the release of the documents. On this basis, access may be refused under section 24(1)(b) of the FOI Act.

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.

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



Dr Mark McDonald

Senior Manager

Prescription Medicines Authorisation Branch

Therapeutic Goods Administration

12 June 2019