



Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-2808789

Ms Mary Montagu

By Email: foi+request-7512-a565af0b@righttoknow.org.au

Dear Ms Montagu,

FREEDOM OF INFORMATION REQUEST FOI 2441
Request Consultation Process

I refer to your request dated 15 June 2021 under the *Freedom of Information Act 1982* (the *FOI Act*) for access to the following documents:

"I write to request copies of all correspondence between the Therapeutic Goods Administration and the Australian Medical Association on the topic of electronic cigarettes sent or received between 15 December 2020 and 15 June 2021 (inclusive)."

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 43 relevant documents 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 relevant 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 relevant third parties of the interim or final decision regarding your request, in the event that a decision is made to give access to documents.

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 15 June 2021, including the terms of your FOI request, and the email to you from the TGA of 30 June 2021, seeking clarification as to whether you seek access to the personal information of third parties, which we have not received a response to;
- the need to prepare at least 32 third party decision letters and associated schedules, should any third parties object to the proposed release of their information. Please note that the number of third parties has been calculated using a sample of documents only, and that there are likely to be many more third parties involved.
- there are additional business areas where searches have not been completed which are likely to have relevant documents, and therefore the total number of documents is likely to be higher than the current estimate;
- the need to prepare a schedule detailing the existing 43 relevant documents;
- the fact that each of those documents may contain business and/or personal information, 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; and
- 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.

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 at least 32 potential third parties;
- considered the time already taken to perform searches for potentially relevant documents (17.25 hours) and the additional time required to complete the remaining searches; and
- estimated how long it might take to process 43 documents, that is, to undertake all the tasks outlined in the previous paragraph.

Based on my conclusion that the processing of your request could take approximately 110.92 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) Regulations 2019*), may, based on the estimated number of hours, exceed \$2,118.38.

Notification of request consultation process

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

I am satisfied that, primarily due to the number of third parties that would need to be consulted, but also including the number of documents involved in your request, 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 from the performance of

their day-to-day functions. This is due to those staff being required to review and consider the documents and any submissions provided by third parties regarding the documents.

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 (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.

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):

- excluding personal information (e.g. the names and contact details of any individuals, or any information that could reasonably identify an individual) of third parties and Commonwealth staff below Senior Executive level.

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.

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

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

Benjamin Noyen
Assistant Secretary
Regulatory Engagement, Education and Planning Branch
Therapeutic Goods Administration
7 July 2021