



Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Ref: D21-2866880

Ms Mary Montagu

By Email: foi+request-7588-8be391a3@righttoknow.org.au

Dear Ms Montagu

FREEDOM OF INFORMATION REQUEST FOI 2441
Notice of Decision

I refer to your request dated 15 June 2021 under the *Freedom of Information Act 1982* (the FOI Act) and subsequent correspondence between you and the TGA in which the scope of your request was clarified as being for access to the following documents:

"I write to request copies of all correspondence between the Therapeutic Goods Administration or its representatives and the Australian Medical Association or its representatives on the topic of electronic cigarettes sent or received between 14 June 2020 and 14 June 2021 (inclusive).

I am not seeking personal information, nor am I seeking duplicates."

Decision maker

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

Decision

I am notifying you of my decision under paragraph 24(1)(b) of the FOI Act to refuse access to the documents that come within the scope of your request.

I am satisfied that, following a request consultation process undertaken in accordance with section 24AB of the FOI Act, a 'practical refusal reason' within the meaning of section 24AA of the FOI Act still exists. Specifically, the work involved in processing your request would substantially and unreasonably divert the resources of the TGA from its other operations.

The reasons for my decisions are set out in further detail below.

Background

In my letter dated 7 July 2021, I notified you of my intention to refuse to give access to documents that come within the scope of your request. As required by paragraph 24(1)(a) of the FOI Act, I undertook a request consultation process in accordance with section 24AB of the FOI Act to provide you with the opportunity to contact a TGA officer to consult them about revising the scope of your request so that the practical refusal request would no longer exist.

Specifically, I informed you that you had fourteen (14) days from the date of receipt of my letter in which to contact the TGA to do one of the following:

- withdraw your request;

- make a revised request; or
- indicate that you do not wish to revise your request.

In your correspondence of 14 July 2021 in response to my letter, you revised the scope of your request as set out above.

Material considered in Decision-Making

In making my decision, I have had regard to:

- the terms of your revised request dated 14 July 2021, in which you had broadened the timeframe of the scope of your request, in addition to confirming that you did not seek access to personal information or duplicate documents;
- the TGA's assessment of the time and resources that would be required to process your revised request;
- relevant provisions of the FOI Act, including sections 24, 24AA and 24AB;
- the guidelines issued by the Information Commissioner under subsection 93A(1) of the FOI Act that I am required to have regard to under subsection 93A(2) of the FOI Act;
- information from relevant areas of the TGA concerning the resources required to comply with your request, and the effect of same on the TGA's operations.

Reasons for Decision

Subsection 24AA(1) of the FOI Act defines when a 'practical refusal reason' will exist in relation to a request. Specifically, that provision states:

- (1) For the purposes of section 24, a ***practical refusal reason*** exists in relation to a request for a document if either (or both) of the following apply:
- (a) the work involved in processing the request:
 - (i) in the case of an agency – would substantially and unreasonably divert the resources of the agency from its other operations; or
 - (ii) in the case of a Minister – would substantially and unreasonably interfere with the performance of the Minister's functions;
 - (b) the request does not satisfy the requirement in paragraph 15(2)(b) (identification of documents).

Subsection 24AA(2) of the FOI Act sets out the matters to which I must have regard in deciding whether a practical refusal reason exists. Specifically, it states:

- (2) Subject to subsection (3), but without limiting the matters to which the agency or Minister may have regard, in deciding whether a practical refusal reason exists, the agency or Minister must have regard to the resources that would have to be used for the following:
- (a) identifying, locating or collating the documents within the filing system of the agency, or the office of the Minister;
 - (b) deciding whether to grant, refuse or defer access to a document to which the request relates, or to grant access to an edited copy of such a document, including resources that would have to be used for:
 - (iii) examining the document; or
 - (iv) consulting with any person or body in relation to the request;
 - (c) making a copy, or an edited copy, of the document;

(d) modifying any interim or final decision on the request.

Subsection 24AA(3) of the FOI Act also sets out the matters to which I must not have regard to:

- (3) In deciding whether a practical refusal reason exists, an agency or Minister must not have regard to:
- (a) any reasons that the applicant gives for requesting access; or
 - (b) the agency's or Minister's belief as to what the applicant's reasons are for requesting access; or
 - (c) any maximum amount, specified in the regulations, payable as a charge for processing a request of that kind.

I confirm that I have not had regard to any of the matters set out in subsection 24AA(3) in coming to my decision.

Following your revision to the scope of the request during the request consultation process undertaken under section 24AB of the Act, the TGA has identified at least 16 third parties who would need to be consulted in relation to the release of the documents.

Based on the preliminary assessment of the number of records and documents that fall within the scope of your request, the time spent on search and retrieval to date and having considered a sample of documents within the scope of your request, I estimate that:

- the search and retrieval (i.e., the time to identify, locate and collate the documents) could take in excess of 20.25 hours to complete;
- the time to individually assess the documents and make a decision in relation to their release (including deciding whether to refuse or grant access or grant access to an edited copy of a document, making copies, conducting consultations with third parties and preparing the decision letter and any third party decision letters) could take over 62.92 hours to complete; and
- the request would take in excess of 78.17 hours for the TGA to process.

Based on the estimated hours it would take to process your request and the need to involve staff from the TGA's regulatory areas to assist in processing the request, I am satisfied that your request would substantially and unreasonably divert the TGA (as part of the Department of Health) from its other operations.

Specifically, staff from the Regulatory Legal Services Branch within the TGA would need to spend a substantial amount of time working on your FOI request to assist in processing and finalising it within the timeframes set by the FOI Act. While undertaking this FOI work, these staff would not be performing their ordinary regulatory functions. This could cause serious delays to and potentially compromise the TGA's role of regulating therapeutic goods under the *Therapeutic Goods Act 1989*. I further note that resources to process your request would also need to be diverted from the Reporting & Collaboration Services Section (being the section responsible for processing FOI requests).

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.

Review and complaint rights

If you are not satisfied with this decision, you can either seek internal review or apply to the OAIC for review of the decision. Further information can be found on the OAIC website at the following link: www.oaic.gov.au/freedom-of-information/reviews-and-complaints/

Should you have any enquiries concerning this matter, please contact the FOI Team on (02) 6289 4630.

Yours sincerely

Authorised and electronically signed by

Benjamin Noyen
Assistant Secretary
Regulatory Engagement, Education & Planning Branch
Therapeutic Goods Administration
21 July 2021