



Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D18-10569496

Dr Jane Quinn

Email: foi+request-4475-a9fa8566@righttoknow.org.au

Dear Dr Quinn

FREEDOM OF INFORMATION REQUEST FOI 275-1718
Notice of Decision

I refer to your request dated 9 April 2018 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

“The number and nature of all adverse event reports submitted for tafenoquine to the TGA adverse events database.”

Decision Maker

I am the Therapeutic Goods Administration (TGA) officer authorised to make this decision under section 23 of the FOI Act. What follows is my decision under the FOI Act.

Scope of the FOI request

The TGA has identified one (1) documents falling within the scope of your request.

Background

On 9 April 2018 the TGA received a request from you under the FOI Act.

On 3 May 2018, you were advised that the processing of your request would be an unreasonable diversion of the agencies resources. You were invited to undertake a Request Consultation Process in an attempt to reduce the scope of your request to a manageable scope.

On 11 May 2018 you provided a revised scope.

On 16 May 2018, you were advised that the processing of your request would still be an unreasonable diversion of the agencies resources. You were invited to reduce the scope of your request to a manageable scope.

On 21 May 2018 you provided a revised scope (as set out above).

On 24 May 2018, the TGA confirmed that a practical refusal reason no longer existed in relation to your request. You were also advised that I had decided not to impose any charges for the processing of your request.

Material Considered in Decision-Making

In coming to my decision I had regard to the following:

- the correspondence between the TGA and yourself;
- the documents falling within the scope of the FOI request;
- all relevant papers in the TGA FOI processing file;
- the provisions of the FOI Act, in particular subsection 22(1) of the FOI Act; and

- the guidelines issued by the Office of the Australian Information Commissioner (OAIC) under section 93A of the *Freedom of Information Act 1982*;

Decision

My decision in relation to the document falling within the scope of the FOI request is to release one (1) document in full.

Given the estimate of charges was a minor amount of \$30.60, I have decided not to impose charges.

Reasons for Decision

Relevant Documents

There is one (1) document that has been identified as relevant to your request. A schedule listing the document along with the document itself is at **Attachment A**.

Under subsection 22 of the FOI Act, irrelevant information which you confirmed you are not seeking has been redacted from the documents as it is considered to be outside the scope of your request.

The reason for the application of section 22 (irrelevant information) to the documents in issue are set out in detail below. A copy of the relevant provision of the FOI Act is at **Attachment B**.

Subsection 22(1): Documents containing information that is irrelevant to the FOI request

The effect of subsection 22(1) of the FOI Act is that where the granting of access to a document would disclose information that is not within the scope of the request and it is possible to provide a copy with information deleted, the agency can do so unless it is evident that the applicant does not wish to be provided access to such a copy. A copy of subsection 22(1) is at **Attachment B**.

The relevant documents contain information that does not fall within the scope of your FOI request. Specifically, the documents contain personal information which you confirmed you were not seeking as part of your request, and information irrelevant to your request. Therefore, I consider this information to be outside the scope of your request.

I consider that to provide you with full access to the documents would disclose information that does not fall within the scope of your FOI request. Accordingly, I have decided that the irrelevant information will be deleted under section 22(1) of the FOI Act and a copy of the documents, with the irrelevant information deleted, will be provided to you.

Release of Documents

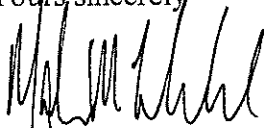
As I have decided not to impose charges, the document is now being released to you.

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. A statement of review rights is at **Attachment C** to this letter.

If you have any queries regarding this matter, please contact Jodie Russell on (02) 6232 8720.

Yours sincerely



Mark McDonald

Senior Manager

Prescription Medicines Authorisation Branch

Therapeutic Goods Administration

24 May 2018