Australian Government

Department of Health
Therapeutic Goods Administration

Dr Jane Quinn
Quinoline Veterans and Families Association

Email: foi+request-4369-47838178@righttoknow.org.au

Dear Dr Quinn

FREEDOM OF INFORMATION REQUEST FOI 208-1718
Request Consultation Process

I refer to your request dated 22 February 2018 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:

> *"Please can you provide the following documents regarding this Schedule 4 approval, and the NCE application (the registration application and pre-submission documents) from which this approval was given:*
>
> 1. *All documents (email correspondence or other written documentation submitted between January 2008 and February 2018) advising the Advisory Committee that the delegate would not consult with them on this application, including any response from the Advisory Committee to this correspondence;*
> 2. *All documents (email correspondence or other written documentation included in the registration application submitted between January 2008 and February 2018) that includes data pertaining to the number and nature of all adverse event reports a) submitted for tafenoquine to the TGA adverse events database, and b) the documentation (email correspondence or other written documentation included in the registration application submitted between January 2008 and February 2018) that contains details of the adverse event reports considered at part of the delegates application review process;*
> 3. *Copies of all sections of the registration application form that contain the detailed consumer (patient) information statements submitted which including dose rates and treatment schedules;*
> 4. *Copies of all sections of the registration application form that contains the detailed medical practitioner's information statements which includes dose rates and treatment schedules;*
> 5. *Copies of all sections of the registration and pre-registration application from for tafenoquine succinate that contains information in the application for registration and / or pre-registration documentation relating to requirements for cytochrome P450 (CYP450) screening in patients prior to treatment with tafenoquine succinate, either for prophylaxis or treatment of malaria.*
> 6. *Copies of all sections of the registration application form for tafenoquine succinate submitted as part of the pre-submission documentation and the registration application regarding toxicity of tafenoquine succinate in humans, or other non-human species, including in-vitro or pre-clinical data. I do not require any personal information to be supplied as part of this FOI request."*

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 1442 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:

- 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 22 February 2018 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 72 documents containing 1442 pages consisting of:
    - 24 electronic files;
    - 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 for 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;
- on 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 five (5) 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:

- considered the actual time spent to date on searching for and retrieving documents for the purposes of your request;
- taken a conservative approach to attributing 3 relevant documents per potential file;
- taken a conservative approach of attributing 60 pages per potential file;
- considered the time required to undertake the consultation process with the five (5) potential third parties;
- considered the time already taken to perform searches for potentially relevant documents and the additional time required to complete the remaining searches;
- taken a sample of ten (10) documents totalling approximately 200 pages and estimated how long it might take to process the sample i.e. to undertake all the tasks outlined in the previous paragraph. I then extrapolated my estimate of the time it would take to process these documents to the total number of pages referred to above that are estimated to be within the scope of the request.

Based on my conclusion that the processing of your request could take approximately 131 hours, I estimate that, calculated by reference to the charges set out in the Schedule to the *Freedom of Information (Charges) Regulations 1982*, that the total charges that may be imposed on you for processing your request may exceed $2,700. 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 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 (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. If you wish to refine the scope of your request you may contact Jodie Russell on (02) 6232 8720.

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.

If you have not contacted the TGA within 14 days of receiving this letter to do one of these things 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

Adrian Bootes
Assistant Secretary
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
21 March 2018