Australian Government

Department of Health
Therapeutic Goods Administration

Dr Jane Quinn

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

Dear Dr Quinn

FREEDOM OF INFORMATION REQUEST FOI 275-1718
Request Consultation Process

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:

> *"Regarding this pre-registration and registration application information pertaining to the registration of tafenoquine succinate, please can you provide the following information regarding this Schedule 4 approval, and the NCE application (the registration application and pre-submission documents) from which this approval was given:*
>
> 1. *The number and nature of all adverse event reports a) submitted for tafenoquine to the TGA adverse events database, and b) the number and nature of those adverse event reports considered at part of the delegates application review process;*
> 2. *The detailed consumer (patient) information statements submitted a) as part of the registration application and b) those approved for tafenoquine succinate including dose rates and treatment schedules;*
> 3. *All 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."*

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 in excess of 5,000 relevant pages that would have to be processed for your request to be finalised. I note in your previous request, the estimated relevant pages was less than the current estimate. As previously advised in our correspondence of 21 March 2018 there were additional areas where searches had not been completed which were likely to have additional relevant documents. Upon a further and more thorough preliminary search and retrieval, the TGA has located more documents in these additional areas resulting in excess of 5,000 relevant pages.

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 9 April 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 in excess of 100 documents consisting of:
    - Over 20 electronic files;
    - potential 10 hard copy files stored offsite;
    - 4 dossiers, which generally contain in excess of 100,000 pages each;
- 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 two (2) 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 5 relevant documents per potential file, both electronic and hard copy;
- taken a conservative approach of attributing 60 pages per potential file, both electronic and hard copy;
- taken a conservative approach of attributing 1000 pages per potential dossier file;

- considered the time required to undertake the consultation process with at least two (2) 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) percent of those documents totalling 200 pages and estimated how long it might take to process the sample ie 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.

Even taking a conservative approach, the processing of your request would likely take in excess of 375 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 would likely exceed $7,900.00. As stated above, this is a conservative estimate and the likely number of pages and hours involved would greatly exceed what I have included in this estimate. However, even taking a conservative approach the estimate of hours and costs involved would be an unreasonable diversion of the Department's resources.

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 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 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.

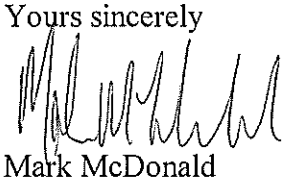
You may wish to consider the following in relation to the scope of your FOI request:

- excluding information that is publicly available, for example Adverse Event Reports are available on the Database for Adverse Event Notifications (DAEN) website via the following link: https://apps.tga.gov.au/prod/DEVICES/daen-entry.aspx;
- limiting the scope to the proposed Product Information (PI) and Consumer Medicine Information (CMI) submitted as part of the registration process only.

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



Mark McDonald
Senior Manager Prescription Medicines Reforms
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
3 May 2018