



Dr Jane Quinn

Email: foi+request-4643-cc2cb25b@righttoknow.org.au and jquinn@csu.edu.au;

Dear Dr Quinn

FREEDOM OF INFORMATION REQUEST FOI 361-1718

Notice of Decision

I refer to your request dated 14 June 2018 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

"The DAEN database identifies 240 adverse event reports lodged for the antimalarial drug mefloquine hydrochloride, also known by the trade name 'Lariam' lodged between 1 January 1980 and 17 February 2018.

Please could you provide me with a detailed list of all adverse events reported for this medication, including date, age of subject and list of adverse event categories selected."

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 14 June 2018 the TGA received a request from you under the FOI Act.

On 15 June 2018 you were advised that the costs for processing your request amounted to \$61.68 and you were asked to pay a deposit of \$20.00.

On 18 June 2018 the TGA received payment in the full amount of \$61.68 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.

The preliminary estimate of charges associated with processing this FOI request was \$61.68. This amount includes the first five hours of decision making at no cost. In accordance with the *Freedom of*

Information (Charges) Regulations 1982 (the Charges Regulations) I have calculated the actual charges that can be imposed for processing your request. In this case, the actual charges that can be imposed are \$70.60. While these charges exceed the estimate of charges previously provided to you, the Charges Regulations provides that a higher amount can be charged if providing full access to the documents. However, given the number of documents and the minor difference between the estimate and actual charges, I have decided not to impose the actual charges.

Therefore, as you have already paid the estimate of \$61.68 in full, the documents are now being released to you.

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



Dr Jane Cook

Head

Pharmacovigilance and Special Access Branch

Therapeutic Goods Administration

21 June 2018

FOI Request 361-1718 in relation to Mefloquine hydrochloride ('Lariam')
The request is for the following:

...“Please could you provide me with a detailed list of all adverse events reported for (Mefloquine hydrochloride ('Lariam'), including date, age of subject and list of adverse event categories selected... lodged between 1 January 1980 and 17 February 2018... I do not require any personal information or individual patient identifiers.”

Schedule of Relevant Documents

| Doc. No. | TRIM Folder Number/Physical File Number | TRIM Document Number/Physical Folio Number | Author | Addressee | Date | Description | Pages | Decision | Relevant Sections |
|-----------------|--|---|---------------|------------------|-------------|--------------------|--------------|-----------------|-------------------------------|
| 1 | FOI361-1718 | DE18-1718 | TGA | TGA | 14/06/2018 | Case Line Listing | 36 | Release in full | s 22 (irrelevant information) |