



Australian Government
Department of Health
Therapeutic Goods Administration

TRIM Ref: D17-718525

Ms Jane Quinn

Email: foi+request-3643-b8ef7d1b@righttoknow.org.au

Dear Ms Quinn

FREEDOM OF INFORMATION REQUEST FOI 323-1617
Notice of Decision

I refer to your request dated 17 June 2017 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 me with the original registration submission and approval documents for the antimalarial drug Mefloquine (trade name 'Lariam'). This would include the full registration application and any subsequent documents, or part thereof, relating to applications or approvals for changes to the dosing schedule."

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 three (3) documents falling within the scope of your request.

Background

On 17 June 2017 the TGA received a request from you under the FOI Act.

On 19 June 2017 the TGA sought clarification in relation to the scope of your request. On the same date you clarified the scope of your request.

On 22 June 2017 the TGA sought further clarification from you in relation to the scope of your request. On the same date, you clarified the scope of your request to the above.

On 28 June 2017 the TGA confirmed the scope of your request to the above and provided you advice in relation to certain documents which fell within in the open access period under the *Archives Act 1983* (Archives Act).

On 5 July 2017 you were advised that the cost of processing your request amounted to \$86.75 and you were asked to pay the full amount of \$86.75. You were also advised at this time of the need to conduct a third party consultation in relation to your request.

On 31 July 2017 the TGA received payment in the full amount of \$86.75 for the processing of your request. The third party consultation was subsequently initiated.

On 8 August 2017 you confirmed you were not seeking any personal information as part of your FOI request.

Material Considered in Decision-Making

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

- the correspondence from you of 17, 19 and 22 including the terms of your FOI request;
- 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 section 22;
- the guidelines issued by the Australian Information Commissioner under section 93A of the *Freedom of Information Act 1982*;
- correspondence between the TGA yourself; and
- consultation with the third party whose documents were involved.

Decision

My decision in relation to the documents falling within the scope of the FOI request is to release three (3 documents in full).

In accordance with the *Freedom of Information (Charges) Regulations 1982* (the Charges Regulations) I have calculated the actual costs associated with processing your request. In this case, the actual charges are the same as the estimate provided to you on 5 July 2017. As you have already paid the full amount of \$86.75, the document can now be released to you.

Reasons for Decision

Relevant Documents

There are three (3) documents that have been identified as relevant to your request. A schedule listing the documents along with the documents themselves is at **Attachment A**.

The schedule indicates for each document my decision to release in full (release). Further, irrelevant information has been redacted under section 22(1) of the FOI Act.

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**.

Documents 1-3 contain information that does not fall within the scope of your FOI request. Specifically, Documents 1-3 contain personal information which you confirmed, in your email of 8 August 2017, you were not seeking.

I consider that to provide you with full access to Documents 1-3 (as identified in the schedule at **Attachment A**) would disclose information that does not fall within the scope of your FOI request. Accordingly, I have decided that the irrelevant information should be deleted under subsection 22(1) and a copy of those documents, with irrelevant information deleted, may be provided to you.

Release of Documents

As you have paid the charges in full for the processing of your FOI request, the documents are 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 Office of the Australian Information Commissioner for review of the decision.

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

Yours sincerely



Adrian Bootes
Assistant Secretary
Prescription Medicines Authorisation Branch
Therapeutic Goods Administration
30th August 2017

FOI Request 323-1617 in relation to Mefloquine

The request is for the following:

Please can you provide... the original registration submission and approval documents, and then any subsequent documentation relating to approval or amendment of dosage for the antimalarial drug mefloquine (trade name 'Lariam'). Please also provide any subsequent approval applications or letters relating to amendment of the aforementioned dosing schedules."

Schedule of Relevant Documents

Doc. No.	File No.	Folio No.	Author	Addressee	Date	Description	Pages	Decision	Relevant sections of the Act
1	1997/14530	1-39	Third Party	TGA	7 May 1997	Application form for Category 1 applications to Vary the Conditions of Registration of mefloquine (Lariam) Update of the Product Information Data and supporting documentation of Category 1 application	47	Release in full	s 22(1) (irrelevant information)
2	1997/14530	40-41	TGA	TGA	5 June 1997	Internal TGA application form	2	Release in full	s 22(1) (irrelevant information)
3	1998/25956	7-15	TGA	Third Party	11 September 1998	Approval letter and approved product information	9	Release in full	s 22(1) (irrelevant information)