Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Ref: D18-110471947

Mr Scott McCormick

Email: foi+request-4816-5ac12d5f@righttoknow.org.au

Dear Mr McCormick

FREEDOM OF INFORMATION REQUEST FOI 826-1819
Notice of Decision

I refer to your request dated 17 September 2018 under the *Freedom of Information Act 1982* (the FOI Act) for access to the following documents:

"I request:

- *release of all correspondence from ADF, AMI and ADHREC (ADMEC) with regard to the ADF Mefloquine and doxycycline malaria prophylaxis trial in Australian soldiers in East Timor, April 2001–October 2001 and October 2001–May 2002. https://www.mja.com.au/journal/2005/182/4/mefloquine-and-doxycycline-malaria-prophylaxis-australian-soldiers-east-timor*
- *any correspondence with regard to amendments in this particular trial protocol."*

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.

Decision

I am notifying you of my decision under section 24A of the FOI Act to refuse your request for access as the documents you have requested do not exist.

Reasons for Decision

Section 24A of the FOI Act states that requests may be refused if all reasonable steps have been taken to find a document and the document does not exist. The relevant electronic databases, files and corporate file lists in the TGA have been searched for the documents you have requested, and following these searches I am satisfied that all reasonable steps have been taken to find the documents requested and that the documents you have requested do not exist.

The ADF trial of malaria medicines to which you have referred was conducted by the Department of Defence. The study was to compare the side effects and effectiveness of mefloquine with doxycycline under typical field conditions. Further information can be found here: http://www.defence.gov.au/Health/HealthPortal/Malaria/AMI_research/mefloquine-doxycycline/default.asp

There is no requirement to notify the TGA of a trial of a medicine for a particular indication where the medicine is already included in the Australian Register of Therapeutic Goods for that indication.

As the trial to which you have referred was a comparative effectiveness/safety trial for two approved goods for their approved indications, there would be no requirement to notify the TGA of the trial and as such the TGA does not hold any documents falling within the scope of your request.

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

If you have any queries regarding this matter, please contact the FOI Team on (02) 6232 8772.

Yours sincerely

Dr Grant Pegg
A/g Head
Pharmacovigilance & Special Access Branch
Therapeutic Goods Administration
\\ October 2018