

# FOI Disclosure log authorisation – FOI 361-1718

## Freedom of Information – Does information about FOI application Number FOI 361-1718 have to be included Disclosure Log?

Request for the number and nature of all adverse event reports submitted for tafenoquine to the TGA adverse events database

### PART I: Documents released to applicant at this time

#### A: Documents released to applicant in response to FOI 361-1718

1. Are any documents to be released to the applicant at this time (or upon payment)?  Yes  No
2. If the answer to Q1 is no, is it because:
- a. The documents could not be found or do not exist; or
  - b. The documents were wholly exempt or subject to reverse FOI; or
  - c. Section 26 (2) applies to this decision (neither confirm nor deny)
  - d. Section 24A applies to the decision (practical refusal)

No entry need to be included in the DL. Go to Question 5.

3. Are there any documents that are subject to reverse FOI? If so, Part II should be completed at the end of the third party (reverse FOI) review period.  Yes  No
4. If the answer to Q1 is yes, list the document number of each document to be released to the applicant now from the schedule attached to the decision letter (whether provided in full or partial) in Table 1.

**Table 1: Publication of documents released to applicant at this time**

(Please attach schedule as provided to the applicant)

Doc No. <sup>1</sup>	Wholly withheld from publication on DL <sup>2</sup>	Partially redacted for publication on DL <sup>2</sup>	Publish on DL as released to applicant <sup>2</sup>	Grounds for exemption under s.11C(1) <sup>3</sup>	Reasons
1			X		

*Reference: 1. Document number from Schedule sent to the FOI applicant. 2. Indicate by ticking in box under relevant heading whether document to be 'wholly withheld from publication on DL', 'partially redacted for publication on the DL', or 'publish on the DL as released to applicant'. 3. Indicate grounds for withholding from publication or redacting: s 11C(1)(a) personal information; s 11C(1)(b) business information; s 11C(1)(c) Information Commissioner Determination; s 11C(1)(d) not reasonably practicable because of extent of modifications.*

If all of the documents released to the applicant are to be wholly withheld then no entry to be included in the DL. Go to Q5.

#### B: Disclosure Log publication decision on FOI 275-1718

5. No information need be included in the Disclosure Log because:
- no documents were released to the applicant because:
    - none were in the scope of the request; or
    - all documents were wholly exempt or subject to reverse FOI; or
    - documents were released to the applicant but all are wholly exempt under s.11C; or
    - Section 26 (2) applies to this decision (neither confirm nor deny)
    - Section 24A applies to this decision (practical refusal)

If this question applies, go to signature.



6. I agree to the information set out in Table 2 being provided to the Departmental FOI team/TGA website team for the purposes of inclusion as an entry in the Disclosure Log?  Yes

**Table 2: Disclosure Log information to be provided to DoH FOI Team and TGA website team for publication**

FOI Number <sup>1</sup>	Date of decision / Access date <sup>2</sup>	Description of FOI request <sup>3</sup>	Number of documents released to applicant and type of release <sup>4</sup>	Other information <sup>5</sup>
361-1718	TBA	Case listing of adverse events reported for (Mefloquine hydrochloride ('Lariam'), between 1 January 1980 and 17 February 2017	1 document released in full	-irrelevant information redacted under section 22(1) of the FOI Act

*Reference: 1. FOI Application Number 2. Date of decision by decision maker and Access date (being the date on which the documents are actually provided to the applicant – usually to be completed later) 3. Short description of FOI request 4. Number of documents being released to the FOI applicant and type of release ie 'full, partial' 5. Whether any not published because of s.11C exemptions eg additional redactions to be made to documents under s.11C(1)(a)/s.11C(1)(b) eg "Section 11C of the FOI Act provides that information that would be unreasonable to publish is exempt from publication. X documents have been identified as reasonable to publish; XX of those documents have had information redacted because of s.11C(1)(a)/(b)."*

7. I agree that the documents referred to in Table 3 be published on the TGA/DoH website under 11C of the FOI Act:

**Table 3: Documents to be published on TGA/DoH website under s.11C of the FOI Act**

Doc No. <sup>1</sup>	Document description (from and to and type)	Publish as provided to FOI applicant? Yes/No	Publish with redactions from that provided to applicant? Yes/No	Grounds for further redaction under 11C(1) and reasons

<sup>1</sup> From schedule that went to applicant.

Signature: \_\_\_\_\_



Name: Dr Jane Cook

Position: Head, Pharmacovigilance and Special Access Branch

Date: \_\_\_\_\_

2/10/2018

**FOI Request 361-1718 in relation to tafenoquine**

**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**

<b>Doc. No.</b>	<b>TRIM Folder Number/Physical File Number</b>	<b>TRIM Document Number/ Physical Folio Number</b>	<b>Author</b>	<b>Addressee</b>	<b>Date</b>	<b>Description</b>	<b>Pages</b>	<b>Decision</b>	<b>Relevant Sections of the Act</b>
1	FOI361-1718	DE18-1718	TGA	TGA	14/06/2018	Case Line Listing	36	Release in full	s22(1)