MEFLOQUINE HCL

#2921 Noted LD 1/4/01

166389

INITIAL INFORMATION

OHIO → EDC, DSEB

SUSPECT ADVERSE REACTION REPORT

Page 1

I. Reaction Information

1. Patient's Initials	1a. Country	2. Date of Birth (Day / Mth / Yr)	2a. Age Yrs	3. Sex	4-6. Reaction Onset (Day / Mth / Yr)
[redacted]	EAST TIMOR	[redacted]	[redacted]	[redacted]	/ JUN / 2001

7. Describe reaction(s) (including relevant test/laboratory data) (Cont'd)

EYE ABNORMALITY
Protocol ID: 252263 033 (AU ARMY SAFETY STUDY) PID:033.001.22054
Protocol Indication: MALARIA

Case reference number [redacted] is a clinical trial report from blinded study 252263/033 for malaria prophylaxis. This report refers to a [redacted]

The patient had no significant medical history at baseline.

The patient received oral study medication from 18 October 2000, to late April 2001 (exact date not specified). Following the six month treatment period, the patient underwent a follow-up examination which revealed eye abnormalities. Angiogram examination of the right eye revealed three pinpoint areas of hyperfluorescence, which faded late in the examination (retinal pigment epithelium window defect). There was no fluorescein leakage. An angiogram examination of the left eye was normal.

LD OTH

The event had not resolved on 01 July 2001. The investigator considered this to be a serious event because it was a serious or a significant side effect, contraindication, precaution or hazard.

The investigator did not specify a relationship between the eye abnormality and treatment with study medication.

8-13. CHECK ALL APPROPRIATE TO REACTION

- ☐ Patient died
- ☐ Involved or prolonged inpatient hospitalization
- ☐ Involved significant disability or incapacity
- ☐ Life threatening
- ☒ Other: Investigator Determined

II. Suspect Drug Information

14. Suspect Drug(s) (include generic name)

CT
252263 (MEFLOQUINE) 252263 Study
SMITHKLINE BEECHAM

20. Did reaction abate after stopping drug? ☐ Yes ☐ No ☒ N/A

15. Daily dose(s)

16. Route(s) of administration
ORAL

17. Indication(s) for use
MALARIA PROPHYLAXIS

POSS.

21. Did reaction reappear after reintroduction? ☐ Yes ☐ No ☒ N/A

18. Therapy dates (from/to)
18-OCT-2000 / -APR-2001

19. Therapy duration

III. Concomitant Drugs and History

22. Concomitant drugs and dates of administration (exclude those used to treat reaction)

23. Other relevant history (eg. diagnosis, allergies, pregnancy with LMP, etc.)

[redacted]

IV. Manufacturer Information

24a. Name and address of manufacturer
SMITHKLINE BEECHAM PHARM

24b. Mfg. Control No. 2001015695-1

24c. Date received by manufacturer
28-JUN-2001

24d. Report Source
☒ Study ☐ Literature
☒ Health Professional

Date of this report
02-JUL-2001

25a. Report Type
☒ Initial ☐ Follow-up

V. Initial Reporter (in confidence)

26.-26a. Name and address of reporter (include zip code)
INVETSIGATOR
NAME / ADDRESS ON FILE

CIOMS I

PRE-PROJECT Blinded

13 JUL 2001

NON-ADRAC TRACK

166389

TIAL INFORMATION

SUSPECT ADVERSE REACTION REPORT Page 2	1. Patient's Initials	1a. Country	2. Date of Birth Day Mth Yr	2a. Age Yrs	3. Sex	Mfg. Control No.
	[redacted]	EAST TIMOR	[redacted]	[redacted]	[redacted]	[redacted]

7. DESCRIBE EVENTS(S) (Cont'd)

Examination	Exam Date	Exam Result
ANGIOGRAM	- -	

Result Text: RIGHT EYE; 3 PINPOINT AREAS OF HYPERFLUORESCENCE (FADE LATE-RPE WINDOW EFFECT), NO FLUORESCEIN LEAK. LEFT EYE;NORMAL.

MEDICAL AFFAIRS SAFETY OFFICER

9 - JUL 2001

GLAXOSMITHKLINE

166389

GlaxoSmithKline

Monday, 9 July 2001

1061 Mountain Highway
Boronia Victoria 3155
PO Box 168 Boronia 3155
Australia

Tel. +61 03 9721 6000
Fax. +61 03 9729 5319
www.gsk.com.au

The Secretary
ADRAC
Australian Drug Evaluation Committee
PO Box 100
Woden ACT 2606

Dear Sir/Madam

Re: Clinical Trial Serious Adverse Event (Local ID# 2921)

Please find attached details regarding a serious adverse event for the following trial:

StudyTitle: Study 033 (AU Army Safety Study). A randomised, double-blind., cpomparative study to evaluate the safety, tolerability and effectiveness of tafenoquine and mefloquine for the porphylaxis of malaria in non-immune Australian soldiers deployed in East Timor.

Study # 252263/033

CTX/CTN #: TBA

Study Drug: Tafenoquine

Comparator Drug(s): Mefloquine

Relationship to Study Drug (causality): Not Stated

Please note that this case was unblinded and the subject has received mefloquine.

Should you have any enquiries regarding this case, please do not hesitate to contact me on [redacted] or directly on [redacted]

Yours sincerely

[redacted]

Medical Affairs Department

13 JUL 2001