DRUG SAFETY & EVALUATION BRANCH
EXPERIMENTAL DRUGS SECTION

OVERSEAS ADVERSE DRUG REACTION REPORT

FOR INFORMATION ONLY

Dr G Dickson
Head EU 2

8 November 2001

Please find attached an Overseas Adverse Drug Reactions Reports from GlaxoSmithKline.

For your information.

EDS
Please request any additional information on outstanding pages

19/11/01

Regards

Rhonda
CTN Officer
EDS

Dr Dickson
Further information as requested
RW 23/11/01

Attached

OS

INITIAL INFORMATION

ORG → EDG, 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]	

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

EYE ABNORMALITY
Protocol ID: 252263 033 (AU ARMY SAFETY STUDY) PID:033.001.22038
Protocol Indication: MALARIA

Case reference number 2001015694-1, is a clinical trial report from blinded study 252263 033 for the prophylaxis of malaria. This report refers to a [redacted]

The patient had no significant medical history at baseline and was receiving no concomitant medications.

The patient received oral study medication from 18 October 2000 to an unspecified date in late April 2001. At the six month ophthalmological assessment the following changes from baseline were found: visual acuity was unaltered, colour vision was reduced by one Ishihara plate, and formal Amsler assessments were normal. On visual examination of the retina minimal to moderate pigmentation of the macula was noted, though it was within normal limits. A single pinpoint area of hyperfluorescence (a retinal pigment epithelium window defect) was observed at the edge of the foveal avascular zone of the left eye. No leakage of dye was noted and the area appeared to correspond to a drusen noted on colour photography. The patient was diagnosed as having an eye abnormality.

The event outcome was not known at the time of reporting. This was considered to be a serious event because it was a significant hazard, contra-indication,

8-13. CHECK ALL APPROPRIATE TO REACTION

- [ ] Patient died
- [ ] Involved or prolonged inpatient hospitalization
- [ ] Involved significant disability or incapacity
- [ ] Life threatening
- [x] Other:

II. Suspect Drug Information

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

252263 (TAFENOQUINE) 252263 Study
SMITHKLINE BEECHAM

15. Daily dose(s)

16. Route(s) of administration: ORAL

17. Indication(s) for use: MALARIA

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

19. Therapy duration

20. Did reaction abate after stopping drug? [ ] Yes [ ] No [ ] N/A

21. Did reaction reappear after reintroduction? [ ] Yes [ ] No [x] N/A

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. 2001015694-1

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

24d. Report Source: [x] Study [ ] Literature [x] Health Professional

Date of this report: 02-JUL-2001

25a. Report Type: [x] Initial [ ] Follow-up

V. Initial Reporter (in confidence)

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

CIOMS I

16 JUL 2001

GlaxoSmithKline

Friday, 6 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# 2919)

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

StudyTitle: Study 033 (AU Army Safety Study)

Study # 252263/033

CTX/CTN #: TBA

Study Drug: Tafenoquine

Comparator Drug(s):

Relationship to Study Drug (causality): Not Stated

Please note that this case was unblinded.

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

16 JUL 2001

GlaxoSmithKline

FAX

To Rhonda Whybrow

Company TGA

Fax 02 6232 8112

From [redacted]

Tel [redacted]

E-mail

Date 23/11/01 Pages including cover 2.

CC

Subject Clinical Trial SAE.

GlaxoSmithKline Australia Pty Ltd
ABN 80 096 307 505
1061 Mountain Highway
PO Box 168
Boronia Victoria 3155
Australia

Tel: +61 3 9721 6000
Fax +61 3 9729 5319
www.gsk.com.au

please find attached Clinical Trial Serious Adverse Event. (Local ID # 2919).

Regards

[redacted]

Noted.
More general action has been taken in relation to this trial because of eye abnormalities.
[illegible signature]
26/4/02

Thursday, 22 November 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

Rhonda Whybrow
Clinical Trials Notification Officer
Drug Safety and Evaluation Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606

Dear Ms Whybrow

Re: Clinical Trial Serious Adverse Event (Local ID# 2919, Patient initials: [redacted]

Thank you for your fax of the 20 November 2001 requesting additional information regarding a Serious Adverse Event for the trial (details below) which was initially reported on 6 July, 2001

As requested I have obtained the following from our Head Office:
This event has has been renamed as 'Retinal changes'.
The final outcome is that the event is ongoing. The nature of these findings (apparent abnormality on fluoroscein angiogram) suggests that they may just be normal variants, and in any case are unlikely to resolve. Therefore further fluoroscein angiography is not planned.

ADRAC #: TBA

StudyTitle: Study 033 (AU Army Safety Study)

Study # 252263/033

Study Drug: Tafenoquine

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

Yours sincerely

[redacted]

Medical Affairs Department

GlaxoSmithKline

Thursday, 22 November 2001

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Yours sincerely

[redacted]

Medical Affairs Department

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	4218
CONNECTION TEL	[redacted]
SUBADDRESS	
CONNECTION ID	GLAXOSMITHKLINE
ST. TIME	20/11 12:37
USAGE T	00'17
PGS. SENT	1
RESULT	OK

TGA THERAPEUTIC GOODS ADMINISTRATION

PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8444 Facsimile: (02) 6232 8241

Department of Health and Aged Care

FACSIMILE

Date:	20 November 2001	**Total pages:**	1
TO:	GlaxoSmithKline Australia Ltd	**Telephone:**	[redacted]
		Facsimile:	[redacted]
ATTENTION:	[redacted]		
Regarding:	Request for further information – AU Army Safety Study trial		
FROM:	Rhonda Whybrow Clinical Trials Notification Officer	**Telephone:**	02 6232 8106
Branch/Div.:	Drug Safety & Evaluation Therapeutic Goods Administration	**Facsimile:**	02 6232 8112

If you do not receive all pages, please telephone the sender immediately

MESSAGE

Dear [redacted]

I wish to acknowledge receipt of the Serious Adverse Event (Local ID# 2919), which was received by the Therapeutic Goods Administration on 16 July 2001.

I have been asked to obtain additional information on the outcome or progress of this event.

Patient Initials: [redacted]
DOB: [redacted]
Country: East Timor

It would be appreciated if you could fax this information to me as soon as possible on (02) 6232 8112.

If you wish to discuss this matter further please contact me on (02) 6232 8106.

TGA THERAPEUTIC GOODS ADMINISTRATION

PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8444 Facsimile: (02) 6232 8241

Department of Health and Aged Care

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Regards

Rhonda Whybrow
Clinical Trials Officer
Experimental Drugs Section
Drug Safety and Evaluation Branch