TGA THERAPEUTIC GOODS ADMINISTRATION
PO Box 100 Woden ACT 2606 Australia
Telephone: (02) 6232 8111 Facsimile: (02) 6232 8112

Commonwealth Department of Health and Aged Care

Patient Category: [redacted] SAS No: 2001/01551
02/04/01

DR . KATCHENEL
ARMY MALARIA INSTITUTE
WEARY DUNLOP DRIVE
GALLIPOLI BARRACKS, ENNOGERA, QLD 4051

Drug : TAFENOQUINE
Patient : [redacted]
Supplier : SMITHKLINE BEECHAM (AUSTRALIA) PTY LIMITED
Dosage : 200MG
Duration : EIGHT WEEKS
Dose Form : TABLET, UNCOATED

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THERAPEUTIC GOODS ACT 1989, S.19
EXEMPTIONS FOR SPECIAL AND EXPERIMENTAL USES
APPROVAL TO SUPPLY UNDER THE SPECIAL ACCESS SCHEME

Concerning your application to use the above drug in the treatment of the above patient on the grounds that there is no alternative therapy currently supplied in Australia, I, the medically qualified person named below, hereby provide a formal Notification of Approval. The proposed clinical use of this drug must be regarded both medico-legally and ethically as experimental. No assurance can be given as to the quality, safety and efficacy in the proposed usage. Your co-operation is required concerning sound data management.

Permission is given for the use of the drug in the above patient for the above duration subject to the following conditions:-

1. The doctor and patient, patient's parent or guardian accept responsibility for any adverse consequence of therapy;
2. The principles set out in the National Health and Medical Research Council's 'Statement on Human Experimentation' is observed;
3. Details of any suspected adverse drug reactions are to be reported to the Australian Drug Evaluation Committee;
4. The TGA be notified of reasons for discontinuation should this occur;
5. On completion of the treatment a detailed patient profile, before and after treatment, is to be submitted to the supplier of this product;
6. On completion of the treatment all remaining supplies of the above product be returned to the supplier;
7. The company supplying the drug accepts responsibility for any defects in the drug related to manufacture, distribution or directions for use including dosage.
8. Special conditions: Nil

DR GRAHAM DICKSON
Drug Safety and Evaluation Branch
Doctor : Please forward a copy to your Chief Pharmacist.
Company copy: Approval notification has been forwarded to the company.

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