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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

Dr George Blackwood
Balmoral Naval Hospital
Middle Head Road
MOSMAN NSW 2088

Dear Dr Blackwood

Re: Tafenoquine

Thank you for your correspondence received 14 April 2000 concerning authorisation to supply Tafenoquine as an unregistered therapeutic good under Section 19(5) of the Therapeutic Goods Act.

Your signed declaration of agreement to treatment directions and evidence of endorsement by the Army Malaria Institute for the purpose of supply of this drug are noted.

Pursuant to subsection 19(5) of the Therapeutic Goods Act 1989, an Instrument authorising you to supply Tafenoquine for use in Defence Personnel only for the treatment of recurrent vivax malaria has been signed. The authorisation is subject to the treatment directions outlined in **Attachment 1.**

This authorisation allows you to prescribe (supply) an unregistered product containing this drug for the specified indication without the need to obtain approval from the Therapeutic Goods Administration (TGA) for each individual patient.

Regulation 47B of the Therapeutic Goods Regulations requires that an authorised prescriber provide the TGA with quarterly reports regarding the supply of an unregistered drug. A suggested format for quarterly reports is at **Attachment 2**. Please note that the first report required will be for the period ending **30 June 2000**. (The information to be provided in the reports is detailed in **Attachment 1**.)

You are reminded that where an unregistered product is intended for use in a clinical trial, an appropriate notification of the trial under the Clinical Trial Notification (CTN) Scheme or approval of the proposed use of the drug for experimental purposes under the Clinical Trial Exemption (CTX) Scheme is required.

Please contact me on (02) 6232 8102 if you have any further enquiries regarding this matter.

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Yours sincerely

Zvonko Hodak
Experimental Drugs Section
Drug Safety and Evaluation Branch
22 May 2000

Attachment 1

TREATMENT DIRECTIONS FOR AUTHORISATION UNDER SECTION 19 (5)

- The product may be prescribed only for patients under the authorised medical practitioner's immediate care.

- The authorised practitioner will obtain informed consent from each patient (or guardian) in relation to the proposed use of the unregistered drug, and in this context, the patient must be informed that is product is **not registered** in Australia.

- The product is not registered for use in Australia. The Therapeutic Goods Administration (TGA) cannot vouch for the quality, safety or efficacy of an unregistered drug, therefore, the use of this product must be regarded as experimental.

- The giving of an authority under subsection 19(5) does not render the Commonwealth, the Secretary or a delegate of the Secretary liable to a person in respect of loss, damage, or injury of any kind suffered by the person as a result of, or arising out of the use of, therapeutic goods by that person or another person.

- The Secretary of the Department of Health and Aged Care may give notice of revocation of this authorisation at any time. This approval is valid until revoked or until this or a similar product is registered in Australia, whichever is the earlier. This condition is imposed in part because to do otherwise would remove any incentive for a sponsor to register such a product in Australia. If you have any interest in the continuing supply, long term, you should ensure that a sponsor is seeking registration of the product in Australia.

- The authorised practitioner will report any suspected adverse reaction to the product to the TGA, preferably using the blue "Report of Suspected Adverse Drug Reaction" pre-paid mailer card that is distributed with the Pharmaceutical Benefits Book.

- The authorised prescriber will submit, every three months, a report of the number of patients for whom the drug has been prescribed, the quantity prescribed for each of those patients and an indication of whether or not prescribing is continuing for each individual patient.

- The authorised practitioner must continue to have an appropriate endorsement in order to continue to supply the drug.

  This means that the authorised prescriber must be a medical practitioner engaged in clinical practice at a hospital and having the endorsement of the ethics committee of the hospital for the purpose of supply of the drug or a medical practitioner endorsed by a relevant specialist medical college or specialist medical society for the purpose of supply of the drug, as required by Regulation 12B(1) of the Therapeutic Goods Regulations.

- The authorised practitioner will comply with all relevant State/Territory requirements.

- The authorised practitioner will instruct the patient or patient's agent to return any unused product to a pharmacy.

Attachment 2

QUARTERLY REPORT -
SUPPLY OF UNREGISTERED DRUGS

Quarterly report by a prescriber authorised under Subsection 19(5) of the *Therapeutic Goods Act 1989.*

Report for the three month period ending: (please circle one)

31 March 30 June 30 September 31 December

Dr Geoarge Blackwood
Balmoral Naval Hospital
Middle Head Road
MOSMAN NSW 2088

DRUG: tafenoquine

Number of new patients commenced on treatment:
(i.e. given initial prescription)

Number of patients continued on treatment:
(i.e. given repeat prescription)

Signature: .....

Date: .....