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Department of Defence
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To:	**The Director** Drug Safety and Evaluation Branch, Therapeutic Goods Administration
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From:	**Capt Graves** 3 RAR RAP HOLSWORTHY NSW 2173
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Subject:	**ENDORSEMENT TO PRESCRIBE TAFENOQUINE**	
Reference:	Date: 31 May 2000	Pages *(including cover)*: 4

Instructions or comments:

1. Please find attached an endorsement from the Army Malaria Institute, treatment protocols, and a signed copy of the agreement to treatment directions.

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ARMY MALARIA INSTITUTE

Weary Dunlop Dve., Gallipoli Barracks, ENOGGERA, 4152

AMI 548-7-41
AMI /00

Mr. Z Hodak
Experimental Drugs Section
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

ENDORSEMENT TO PRESCRIBE TAFENOQUINE

The Army Malaria Institute endorses

Dr. Martin Gomes, RMO 3RAR.

to be an authorised prescriber of Tafenoquine under the prescribing direction provided by the Institute.

Prescribing of Tafenoquine endorsed by the Army Malaria Institute

Tafenoquine is an aminoquinolone analogous to Primaquine. Primaquine is presently recommended by the Army Malaria Institute (AMI) for the eradication and treatment of Vivax Malaria. Tafenoquine has been trialed by AMI in both Bougainville and East Timor for eradication and treatment. It has been found to be effective and safe. This supports trials conducted by SmithKline Beecham, the manufacturer of Tafenoquine.

AMI directs prescribing of Tafenoquine for the purposes of treating recurrent Vivax Malaria in Defence Personnel after initial treatment with Chloroquine (IAW HPD215). For endorsement to prescribe Tafenoquine in treatment of recurrent Vivax Malaria, the following requirements must be met by the endorsed and prescribing medical officer:

- Discussion of each case with the AMI Medical Officer on call (T: 0407 150384),
- Diagnosis of recurrent Vivax Malaria and the primary episode of Vivax Malaria must be confirmed to AMI (to the satisfaction of the OC Clinical Field, AMI) prior to use of Tafenoquine,
- The case will be treated with Chloroquine initially IAW HPD215,
- The patient will be informed of the nature and potential side effects of Tafenoquine and this is to be recorded in the Patient Medical Documents,
- Tafenoquine treatment is to begin prior to any further evidence of Vivax Malaria (usually within one week of concluding Chloroquine treatment),

- The protocol for Tafenoquine shall be:
  - 200mg base daily for three days
  - followed by 200mg base weekly for eight weeks.
- Provision of blood slides (thick and thin film) or samples (should PCR be required for diagnosis) with results of a full blood count and liver function tests are required:
  - Prior to onset of treatment with Chloroquine (IAW HPD215),
  - Following treatment with Chloroquine,
  - Following treatment with Tafenoquine and
  - On the occurrence of any intercurrent illness requiring medical attention during the course of the treatment program, or
  - In the event of any recurrence of Vivax Malaria in the following 12 months.

M D EDSTEIN
LTCOL
DEPUTY DIRECTOR, AMI

Tel: 07 3332 4930; Fax: 07 3332 4800

14 April 2000

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AGREEMENT TO TREATMENT DIRECTIONS

AUTHORISATION OF PRESCRIBERS UNDER SECTION 19(5) OF THE THERAPEUTIC GOODS ACT 1989

Unregistered drug to be supplied (prescribed): TAKEDA QUINE.

Route of administration / dosage form: ORAL.

Condition / reason for prescribing: RECURRENT VNAT MALARIA.

Supplier's name and address: SK-B. / ARMY.

Name of Body endorsing this application: ARMY MALARIA INSTITUTE.

I understand that:

- the product is not registered for marketing in Australia and that the Therapeutic Goods Administration (TGA) is unable to vouch for the quality, safety or efficacy of this unregistered product, and that its use is 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 product may be prescribed only for patients in an authorised prescriber immediate care.
- an authorised prescriber must continue to have an appropriate endorsement in order to supply the drug.

  That is, an authorised prescriber must be a medical practitioner engaged in clinical practice at a hospital and having the endorsement of the ethics committee of that hospital for the purpose of supply of that drug; or a medical practitioner endorsed by a relevant specialist medical college or specialist medical society for the purpose of supply of the drug.
- the Secretary of the Department of Health and Aged Care may give notice of revocation of this authorisation at any time and that any authorisation would be valid only until revoked or until the specified product or a similar product is registered in Australia, which ever is the earlier.

I agree to:

- obtain from each patient (or guardian) consent in relation to the proposed use of the unregistered product, and in this context, inform the patient that the product is not registered in Australia.
- report any suspected adverse reactions to the TGA.
- to provide the TGA with a quarterly report on the number of patients for whom I have prescribed the product.
- to comply with all relevant State/Territory legislation.

Signature: [signature] Date: 30/5/00

Medical Practitioner's name and address: CAPT Martin Graves
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KARYONG LINES
LIVERPOOL MILITARY AREA