## +0252328112 DRUG EVALUATION

SEP 26 '00 11:04

Thempeuto Goods Administration REQUEST FOR SPECIAL ACCESS SCHEME (SAS) APPROVAL CATEGORY B and C PATIENTS ONLY

Category B: Persons suffering from a life-threatening medical condition,

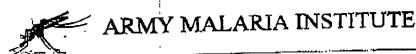
even if they are not critically ill.

Category C: Persons suffering from a serious but not life-threatening illness.

Commenced in Department. Health and Family Service

	PLEASE USE BLACK PEN, PRINT CLEARLY	AND COMPLETI	EALLSECTIONS
rescribing	doctor details		
Name	I SEIDL	Hospital	ADF.
Pessal	RAWO 5/7 MAR	Dapaument	5/7 RAR (MECH)
address	LOBERTSON BANNACH)	Phone number	(08) 8935 3057
	PARMORDIN. NT		
	Postcade 0 630	Fax number	(08) 1431 3050
rug deteils	5		≥ 89353022.
Active	TAFENOQUINE	Trad	e name
ingredient	TATENOQUIVE	CompanyA	supplier SKI3
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		E BAS No.	
Diagnos	Vivax malaria		
ustificatio	in for use of drug (include previous and surrent treatment; a	ale whether reque	sling renewal of SAS approver)
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	ment vivax malaria as per	pi otocei	711111
Malar	la lostitute.	***	
Prescribit	ng doctor DR ISAAC SEIDL		
9	Signature		Date 30/4/0]
100	Fax to: The Experimental Drugs Team or Send (02) 5232 9112	To	ne SAS Officer SA D Box 100

Woden ACT 2608



Weary Dunlop Dve., Gallipoli Barracks, ENOGGERA, 4152

AMI 548-7-41 AMI /01

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

## ENDORSEMENT TO PRESCRIBE TAFENOQUINE

The Anny Malaria Institute endorses

Dr. Isaac Soidl, 5/7 RAR, Darwin.

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 Glaxo SmithKline, the manufacturer of l'afenoquine.

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),

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- The protocol for Tafenoquine shall be:
  - 200mg base daily for three days
  - followed by 200mg base weekly for eight weeks.
- Provision of blood samples are required:
  - Prior to onset of treatment with Chloroquine (IAW HPD215), Smear, FBC, LFT
  - Following treatment with Chloroquine, immediately prior to onset of treatment with Tafenoquine,
    Smear, FBC. LFT
  - Pollowing treatment with Tafenoquine, 12 hours after the final dose (including separation of plasma for drug levels),
     Smear, FBC, LFT, plasma for TQ levels
  - At week 2 and week 6 after commencement of the loading dose samples should be collected within 2 hrs of receiving the next weekly dose (ie., trough steady-state levels of Tafenoquine),
     Smear, FBC, LFT, plasma for TQ levels
  - At week 4 and week 8 after commencement of the loading dose samples should also be collected at about 12 hours post-dosc (ie., peak steady-state Tafenoquine levels), Smear, FBC, LFT, plasma for TQ levels and
  - On the occurrence of any intercurrent illness requiring medical attention during the course of the treatment program,
     Smear, FBC, LFT, plasma for TQ levels or
  - In the event of any recurrence of Vivax Malaria in the following 12 months Smear, FBC, LFT, plasma for TQ levels.

M D EDSTEIN

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DEPUTY DIRECTOR, AMI

Tel: 07 3332 4930; Fax: 07 3332 4800

02 Feb. 01