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

Commonwealth Department of Health and Aged Care

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Dr John Simpson
Lavarack Barracks Medical Centre
Military Post Office
TOWNSVILLE QLD 4813

Dear Dr Simpson

Re: Tafenoquine

I refer to your facsimile received on 11 September 2000, concerning supply of an unregistered product containing Tafenoquine.

Pursuant to Section 19(1)(a) of the Therapeutic Goods Act 1989, approval is granted for the supply of tafenoquine for patient [redacted]

This approval is granted on the grounds that there is no suitable alternative therapy marketed currently in Australia. The Therapeutic Goods Administration can give no assurance as to the quality, safety and efficacy of this drug product in the proposed usage. It should be noted that the proposed clinical use of the drug must be regarded as both medico-legally and ethically as experimental.

All parties involved in the supply of unregistered drugs need to recognise that the practice may carry medico-legal risk and, in the case of a company, there may be implications for the company's indemnity. The TGA does not give any assurances or indemnity in regard to the supply of unregistered drugs.

An Australian company supplying an unregistered therapeutic good is required to keep records relating to the source of supply, distribution and disposal of this unregistered product, and, if requested by the Secretary of this Department, supply the records to the Secretary.

Permission is given subject to the following:

1. Approval is given for the supply of tafenoquine at a loading dose of 200mg daily for three days then 200mg once a week for 8 weeks.

2. This approval is valid for up to six (6) months from the date of this letter or until revoked or until tafenoquine is marketed in Australia, whichever is sooner.

3. The total quantity supplied must not exceed that required for use as described in the patient identified in the request.

4. The approval is for supply for use in the patient named on the application

5. The product is used within the context of fully informed consent. The product is currently unregistered in Australia and the proposed use constitutes use as an experimental drug.

6. The doctor and patient or patient's guardian accept responsibility for any adverse consequence of therapy.

7. The principles set out in the National Statement on Ethical Conduct in Research Involving Humans are observed.

8. Details of any suspected adverse drug reactions are reported to the TGA.

9. The TGA is notified of reasons for discontinuation should this occur.

10. The Commonwealth accepts no responsibility for any defects in the product related to manufacture, distribution or directions for use, including dosage.

This decision is an "initial decision" within the meaning of s 60 of the Therapeutic Goods Act 1989 ("the Act"). This means that if your interests are affected by the decision, you may seek reconsideration by the Minister. Any appeal should be made in writing within 90 days after this decision first comes to your notice or to the notice of your company, and should be sent to the following address:

The Parliamentary Secretary to the Minister
for Health and Aged Care
Parliament House
CANBERRA ACT 2600

The letter should be headed "APPEAL UNDER S 60 OF THE THERAPEUTIC GOODS ACT 1989".

Before embarking upon this course of action you are invited to contact the initial decision maker to see whether the matter can be resolved informally.

The Parliamentary Secretary may either deal with the appeal personally, or send it to be dealt with by one of the Minister's delegates within the Department. Should you be dissatisfied with the result of your appeal then, subject to the Administrative Appeals Tribunal Act 1975, you may appeal to the Tribunal for review of the Minister's/Delegate's decision.

If you require further assistance regarding this matter, please contact the Drug Safety and Evaluation Branch on 02 6232 8113.

Yours sincerely

Dr G Dickson
DELEGATE OF THE SECRETARY
18 September 2000