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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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Major Scott Kitchener
Army Malaria Institute
Weary Dunlop Avenue
Gallipoli Barracks
ENOGGERA QLD 4152

Dear Major Kitchener

I refer to the requests from Dr John Simpson, Dr Peter Zaffia and Dr Martin Graves to be authorised under subsection 19(5) of the *Therapeutic Goods Act 1989* (the Act) to supply tafenoquine. I also refer to the recent authorisation given to Dr George Blackwood to supply tafenoquine.

Paragraph 19(6)(a) of the Act provides an authority under subsection 19(5) may only be given to practitioners included in a class of medical practitioners prescribed by the *Therapeutic Goods Regulations 1990*. Regulation 12B states:

> For the purposes of paragraph 19(6)(a) of the Act, each of the following classes of medical practitioners is prescribed in relation to medicines:
>
> (a) medical practitioners, each of whom:
> (i) is engaged in clinical practice at a hospital; and
> (ii) is endorsed by the ethics committee of the hospital for the purposes of that paragraph;
>
> (b) medical practitioners, each of whom:
> (i) has specialist qualifications; and
> (ii) is endorsed by a relevant specialist medical college or specialist medical society for the purposes of that paragraph;
>
> (c) medical practitioners, each of whom:
> (i) is engaged in general practice; and
> (ii) is endorsed by a relevant specialist medical college or specialist medical society for the purposes of that paragraph;
>
> if the college or society recognises that:
>
> (iii) the practitioner has particular expertise in treating the relevant condition or conditions; or
>
> (iv) the practitioner works in a remote locality where medical specialists are not available, or not readily available, to fulfil the need in the locality for supplying specified medicines or specified classes of medicines.

It appears that the medical practitioners who have sought authorisation under subsection 19(5) of the Act do not fall within any of the classes of medical practitioners prescribed in Regulation 12B(1). Accordingly, they cannot be authorised under subsection 19(5) of the Act to supply tafenoquine.

As the authorisation given to Dr Blackwood was given to him on the grounds that he was a medical practitioner within Regulation 12B(1)(a), this authorisation should not have been made. A letter to Dr Blackwood advising him of this issue will be sent under separate cover.

As you are aware, there are provisions under the Act whereby unregistered therapeutic goods can be supplied in special circumstances. Subsection 57(2) of the Act provides that the Secretary of the Department of Health and Aged Care may delegate the power to approve the supply of unregistered therapeutic goods to a medical or dental practitioner or a pharmacist. This provision has been used previously to authorise medical practitioners in the Defence Forces to supply primaquine. The option of using a delegation under section 57 of the Act was raised with you. However, we have since been advised by Major Sue Turner that the office of the Director General of Health Services for the Army does not wish for this mechanism to be used for the supply of tafenoquine.

In this case, the doctors may wish to apply to the TGA on a case by case basis to supply tafenoquine under the Special Access Scheme (SAS). It was our understanding that the patients to be treated with tafenoquine are those who do not satisfy the selection criteria for the trial of tafenoquine being conducted by the Army Malaria Institute and that the number of patients will be quite small (anticipated number - 12). This should not be burdensome for the medical practitioners concerned.

Further information on arrangements for supply under the SAS can be obtained from Nicole Steinberg, Senior Pharmacist in the Experimental Drugs Section on (02) 6232 8125.

Yours sincerely,

Graeme Harris

Graeme Harris MBBS BMedSci
Medical Advisor
Experimental Drugs Section
Drug Safety and Evaluation Branch

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cc Colonel Neale Burton
Director of Health Resources
Defence Health Service Branch
CP2-7-2
Department of Defence
CANBERRA ACT 2600