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File: 1999/46867

Folio: 75

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

Dear Dr Blackwood

Re: Authorisation to prescribe Tafenoquine under section 19(5) of the *Therapeutic Goods Act 1989*.

I refer to the instrument made on 19 May 2000 under subsection 19(5) of the *Therapeutic Goods Act 1989* (the Act) authorising you to supply tafenoquine to Defence Personnel for the treatment of recurrent vivax malaria.

Paragraph 19(6)(a) of the Act provides that 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* (the Regulations). 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.

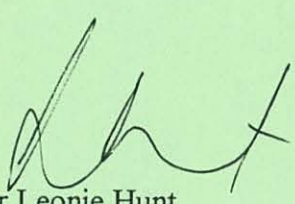
The authorisation given to you was given as a medical practitioner included in the class of medical practitioners prescribed under paragraph 12B(1)(a) of the Regulations, that is, 'medical practitioners engaged in a clinical practice at a hospital and endorsed by the ethics committee of that hospital for the purposes of subsection 19(6) of the Act'.

It has been brought to my attention that you do not satisfy these requirements and, therefore, the authorisation should not have been issued. Accordingly, you are no longer authorised to supply or prescribe tafenoquine for use in Defence Personnel for the treatment of recurrent vivax malaria.

Please note that your patients will not be disadvantaged as approval to supply tafenoquine can be sought under the provisions of section 19(1) of the Act, that is, through the Special Access Scheme.

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



Dr Leonie Hunt
Branch Director
Drug Safety and Evaluation Branch

19 July 2000

cc Chief Executive Officer ✓
Balmoral Naval Hospital
Middle Head Road
MOSMAN NSW 2088