



Lea McAuley  
19/07/2000 11:02

To: Graeme Harris/TGA/Health@Health\_gov\_au  
cc: Terry Lee/TGA/Health@Health\_gov\_au, Jeff Ibbotson/TGA/Health@Health\_gov\_au, Janice Larkin/TGA/Health@Health\_gov\_au

Subject: Subsection 19(5)

Graeme

I have set out my comments below.

### 1. Letter to Dr Blackwood

I have set out the following amendments to the first two paragraphs on page 1. Page 2 is fine .

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*. Regulations 12B states:

[As per your letter]

### 2. Letter to 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 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*. Regulations 12B states:

[As per your letter]

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 ... .

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 ...

In this case, you may wish to apply to the Secretary to be authorised, on a case by case basis, to supply tafenoquine under the Special Access Scheme (SAS). It was our understanding ... .

I am happy to discuss the above advice.

Lea McAuley.  
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