

● Nicole Steinberg

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To: Kerri Mackay/TGA/Health@Health_gov_au
cc: Graeme Harris/TGA/Health@Health_gov_au

Subject: Tafenoquine and external delegation

Kerri

This is the background information relating to the tafenoquine issue and the Army Malaria Institute (AMI).

The AMI submitted 19(5) applications for a number of their doctors to prescribe tafenoquine to patients that fell outside the guidelines of the clinical trial that they were conducting. The doctors had been endorsed by the AMI which is not a suitable endorsing body for a 19(5) application under Regulation 12B and nor is the ethics committee of the Health Services of the Defense Forces an appropriate endorsing body under this regulation.

It was, therefore, suggested to Major Scott Kitchener that it could be arranged for tafenoquine to be added to the list of drugs, which the army has external delegation to approve supply under s.57 of the Act. Major Kitchener was told that in the interim, if there were urgent cases the TGA would be happy to accept SAS applications.

The issue had been sitting dormant for a few weeks, in which time we had not received any SAS applications from Major Kitchener.

This week, I began looking into external delegation and it was brought to my attention that the AMI would need to submit a letter, addressing a number of criteria, to the TGA. The letter would have to be over the signature of the Director General of the Health Services for the Army. I informed Scott of this on Wednesday, at which time he submitted a letter to the Director General for his signature.

Major Sue Turner (ph. 6266 3924) received this letter and her phone call, via yourself, was seeking further information about external delegation and why the AMI doctor's had applied for it. I explained to her why the army's ethics committees were inappropriate endorsing bodies and that it was our suggestion that they seek to add tafenoquine to the list of drugs they have external delegation over.

She discussed it with Colonel Neale Burton, her supervisor, and the conclusion was that he is not happy for the army doctor's to have external delegation to prescribe this product and he would prefer that it be dealt with via the SAS. She reiterated Scott's sentiment that there would only be a handful of patients (approx. 12) requiring tafenoquine under SAS.

I told her that it was their choice whether they choose to sign the letter or not and that the TGA would be prepared to accept applications under the SAS for tafenoquine.

Regards

Nikki

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