Inspector-General of the Australian Defence Force

2015/
IGADF/OUT/2016/

Mr Colin Brock

Dear Mr Brock

1. The Inspector-General of the Australian Defence Force (IGADF) is tasked to provide a means of review and audit of the military justice system independent of the ordinary chain of command. In particular, IGADF is tasked to ensure Australian Defence Force (ADF) personnel are treated fairly and in accordance with current policy.

2. On 07 September 2015, an Army member lodged a wide-ranging submission with the IGADF alleging unethical and unlawful use by Defence of the anti-malarial drug mefloquine, particularly in relation to clinical trials of conducted by the Australian Army Malaria Institute (AMI) involving ADF personnel deploying to East Timor during the period 2000 to 2002. The allegations included that participation in the trials was not voluntary in that Defence members were compelled to take part as a condition of deployment to East Timor, and were not informed of the possible adverse side effects of the drugs.

3. On 11 September 2015, the IGADF decided to inquire into military justice issues identified in the submission and appointed an Assistant IGADF for this purpose. The principal focus of the Inquiry was to determine whether relevant processes and protocols existing at the time for the conduct of the trials were observed, including an examination of the issues of voluntary participation and informed consent. The Inquiry did not examine the general use of mefloquine or tafenoquine by Defence members, or the side effects that may be caused by those anti-malarial drugs, as these issues fall outside IGADF's military justice jurisdiction.

4. On 10 May 2016 you were interviewed by the Assistant IGADF, your name having been provided to the Inquiry by the Army member (complainant) as a participant in the 1st Royal Australian Regiment (1 RAR) tafenoquine trial, and willing to provide evidence on the voluntary nature of participation in that trial. I wish to advise you that the Inquiry has now concluded and inform you of the key outcomes.

5. During your interview you stated that the then Commanding Officer (CO) of 1 RAR addressed the battalion on the parade ground about 1 RAR's participation in the anti-malarial drug trial, and said words to the effect that if soldiers did not participate in the trial they would not deploy to East Timor. Furthermore, you indicated that you did not misinterpret encouragement, or an expectation by the CO of participation, as a direction or threat that non-participation in the trial would result in non-deployment.

6. There was some evidence received from other witnesses that was generally (although not completely) consistent with your evidence. Witnesses (including you) honestly believe their memory is based on what they actually remember and not from what others have told them, or they have read on *Facebook* or in the media.

7. However, there was also contradictory evidence received from other former members of 1 RAR that the trial was voluntary, and none of those witnesses ever heard CO 1 RAR give a direction, or make a threat to the battalion soldiers, using words to the effect if they did not participate in the trial they would not deploy. Numerous of those witnesses had a good memory of the pre-deployment phase, including the medical briefings and the CO addressing the battalion. Their evidence corroborated CO 1 RAR's account in most aspects, in particular, that he addressed the battalion on the benefits of trialling a new anti-malarial drug, that participation in the trial was voluntary, that he supported the trial and that he would be participating.

8. The Inquiry found that CO 1 RAR did not threaten soldiers with non-deployment if they did not participate in the trial. However, there was clearly strong encouragement to participate in the trial from CO 1 RAR, and the benefits of the trial were promoted by the AMI medical investigators. Given the intensity of a pre-deployment environment, it is considered possible that some of those present for the CO's address, interpreted the CO's strong words of encouragement in a manner not intended, namely, as an implied threat or direction to participate in the trial if they wanted to deploy.

9. Overall, the Inquiry found both anti-malarial drug trials were conducted ethically and in compliance with National Health and Medical Research Council National Guidelines, with special care taken to allow for the hierarchical Defence command environment. The trials were voluntary and participants were provided with information about side effects, which was consistent with relevant product and consumer medicine information available at that time.

10. As a result of evidence provided by you and other 1 RAR, 2 RAR and 4 RAR trial participants, I have made a recommendation to Joint Health Command concerning the conduct of trials in the hierarchical Defence organisation. I have found that the potential for acceptance by soldiers of advice or encouragement provided to them by military persons in authority, combined with a potential belief that participation in the trials was expected, is an issue warranting further consideration in the conduct any future medical trials, particularly in the context of pre-deployment activities for an overseas operation.

11. I wish to further advise you that it is likely there will be a public release of the IGADF report, which will be appropriately redacted for privacy, meaning that your name and other material, which could identify you, will be 'blacked' out.

12. Thank you for your assistance to this Inquiry.

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Yours sincerely

JM Gaynor, CSC
Brigadier
Acting Inspector-General Australian Defence Force

BP25-4-106
Office of the Inspector-General ADF
PO Box 7924
CANBERRA BC ACT 2610

28 September 2016

DEPARTMENT OF DEFENCE
AUSTRALIAN ARMY MALARIA INSTITUTE

Gallipoli Barracks, Enoggera, Queensland 4052
Phone: + 61 (0)7 3332 4801 Fax: +61 (0)7 3332 4800

Tafenoquine Trial

Dear Mefloquine Subject

CLARIFICATION ON YOUR PARTICIPATION IN THE TAFENOQUINE VS MEFLOQUINE TRIAL

1. Due to a clerical error at this end, many of you would have received both a letter indicating that you had been on Tafenoquine and another indicating Mefloquine during the trial in East Timor conducted by AMI.

2. If you receive this letter it is confirmation that you were in the **Mefloquine** group and any comment or returns required for those on Tafenoquine do not apply. The medication you received is a currently registered anti-malarial which has been extensively used with an excellent safety profile and was not associated with any of the eye changes commented on in Tafenoquine letter which was mistakenly included in your mail out.

3. Apologies for our error in sending out the wrong information. There is no requirement for you to either respond to this correction or to the original mailout.

4. Again thankyou for your assistance with this valuable research.

Yours faithfully

PETER NASVELD
Lieutenant Colonel
Principal Investigator

11 November 2003

DEPARTMENT OF DEFENCE
JOINT HEALTH SUPPORT AGENCY ARMY MALARIA INSTITUTE

WEARY DUNLOP DRIVE
GALLIPOLI BARRACKS, ENOGGERA 4051 QLD AUST

548-7-41

OP CITADEL

Dosing with the study drug TAFENOQUINE

In 2000-2001 you were given the drug TAFENOQUINE for up to 6 months under my care, as part of a malaria study to assess the safety and effectiveness of this drug that is under development by the drug company GlaxoSmithKline and the US Army. This study was run by the Australian Army Malaria Institute (AMI) in East Timor.

Nearly 3000 people, including yourself, have been given TAFENOQUINE in studies. These people have been recruited from Australia, Asia, Africa, Europe and the United States. No serious problems, or long term effects, have been reported with TAFENOQUINE since dosing began in humans over 5 years ago.

In the study in East Timor in soldiers given TAFENOQUINE for 6 months, a group of the soldiers had additional examinations of their eyes – both before the study began, and at the end of the study after taking the drug for 6 months. In this group many of the soldiers who received TAFENOQUINE developed tiny deposits on the front of their eyes (the cornea). It is important for you to know that none of these soldiers had any symptoms – their vision was not affected in any way. Exactly the same changes are seen with other drugs used all over the world for a variety of diseases and conditions. This includes the drug chloroquine that has been used for many years in treating and preventing malaria. With all these drugs it is also important for you to know that these deposits disappear completely, given time. We know from the examinations in the soldiers that, for TAFENOQUINE, deposits disappear after about 6 months. We do not believe these deposits have any long-term effects on your eye or your vision.

A group of expert eye doctors from all over the world met in America to review the findings in the soldiers and provide advice. They agreed that these deposits were of little concern, would completely disappear with time, they do not affect vision, and are not a reason to stop taking drug. This group of doctors also reviewed other examinations on these soldiers – such as how well they could read letters on a chart, colour vision, and looking at the back of the eye. They confirmed that none of the soldiers had suffered any loss of vision as a result of taking TAFENOQUINE.

We hope you find this information reassuring, in that there is currently no evidence that vision has been affected in any subject given TAFENOQUINE. As you finished your study more than 1 year ago, these totally harmless deposits are extremely unlikely to be present.

However, if you are still concerned, you may want to contact your local doctor or clinic for further advice. Please, make an appointment by contacting your local Regimental Aid Post or Medical Centre for initial assessment. If your doctor thinks that further specialist assessment is required, he/she will then contact us at the Malaria Institute to arrange suitable follow-up.

You should take a copy of this letter with you to your appointment so that your doctor can advise us of any findings or follow-up required. Additionally, we would appreciate it if you could sign and date the copy of the letter included and return it to us in the pre-paid envelope provided so that we can be sure that this information has reached you. Alternatively, you may wish to acknowledge receipt or seek clarification by emailing the Principal Investigator at the email address listed below.

Yours sincerely

PETER NASVELD
Lieutenant Colonel
Principal Investigator

18 September 2003

DEPARTMENT OF DEFENCE
JOINT HEALTH SUPPORT AGENCY ARMY MALARIA INSTITUTE

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OP CITADEL

YOUR INVOLVEMENT IN THE AMI TAFENOQUINE VS MEFLOQUINE TRIAL

1. Firstly I would like to thankyou for your involvement in the important malaria drug trial which was conducted in East Timor in late 2000 through to mid 2001. Your involvement made it possible for the ADF to comprehensively evaluate Tafenoquine, the trial drug, but also to get valuable information on the comparator drug, Mefloquine. During the trial, you were on the comparator anti-malarial medication, **Mefloquine**. Mefloquine has been is use for over 15 years and is considered very effective and safe. Some people have been known to experience mood changes and vivid dreams on Mefloquine but the vast majority of people tolerate the drug very well.

2. The study is now complete and the findings indicate that both drugs were very effective in protecting you against malaria.

3. Some interesting findings were identified when we looked closely at some of the study participants. These were:

   a. Some participants in the Tafenoquine group developed a deposit of pigment in the cornea (the skin covering the eye). These soldiers were comprehensively followed up over a 12 month period and the deposits disappeared. They were not associated with any difficulties with vision.

   b. There was also a trend that Creatinine (a measure of how well your kidneys are working) in your blood was increased during the 6 months on the trial. This occurred in both the Tafenoquine and the Mefloquine participants. A further follow up study to evaluate this was commenced in September 2002 and has just been completed where we looked at 187 soldiers who had showed this change. Analysis of these results now allows us to clearly conclude that there is no evidence that either Tafenoquine or Mefloquine produces chronic problems with the kidneys.

4. The clinical trials of Tafenoquine are now contiuing and it is hoped that this effective drug will find its way into the ADF arsonal against malaria within the next few years. Further evaluation of Tafenoquine was stopped until follow up study to clarify these two issues was undertaken by both the US Army and AMI.

5. Again I would particularly like to thankyou for your participation. Notations have been included in your Unit and Cenral Medical Records and AMI will retain details of your involvement for up to 75 years should any areas of future concern be identified.

Yours sincerely

[redacted]

PETER NASVELD
Lieutenant Colonel
Principal Investigator

[redacted]

18 September 2003