INSPECTOR-GENERAL OF THE
AUSTRALIAN DEFENCE FORCE

INQUIRY REPORT INTO ISSUES
CONCERNING
ANTI-MALARIAL TRIALS OF THE DRUG
MEFLOQUINE BETWEEN 2000 AND 2002
INVOLVING AUSTRALIAN DEFENCE
MEMBERS DEPLOYING TO EAST TIMOR

INSPECTOR-GENERAL OF THE AUSTRALIAN DEFENCE FORCE
LEVEL 4, 25 BRINDABELLA CIRCUIT, CANBERRA AIRPORT, ACT 2609
Left blank intentionally
INSPECTOR-GENERAL OF THE AUSTRALIAN DEFENCE FORCE
INQUIRY REPORT INTO ISSUES CONCERNING
ANTI-MALARIAL TRIALS OF THE DRUG MEFLOQUINE BETWEEN 2000 AND 2002
INVOLVING AUSTRALIAN DEFENCE MEMBERS DEPLOYING TO EAST TIMOR

SUMMARY OF FINDINGS AND RECOMMENDATIONS

DIRECTION 1:

Review the circumstances of the alleged trial use by Defence of mefloquine during the period 2000-2002 and determine, in consultation with relevant subject matter experts, if this use was reasonable and consistent with relevant Health protocols and policies at this time.

FINDING 1: Mefloquine is an approved and registered anti-malarial drug with the Therapeutic Goods Administration (TGA), and was used by Defence in two clinical studies (field trials) in the period 2000 to 2002. The trials were conducted by the Army Malaria Institute (AMI), a specialist medical research unit, and involved Australian battalion groups deployed to East Timor.

FINDING 2: The AMI study protocols for the two clinical drug trials were reviewed and approved by the then Australian Defence Medical Ethics Committee (ADMEC), now the Australian Defence Human Research Ethics Committee (ADHREC), a committee of impartial experts responsible for ensuring such trials are both ethically permissible and scientifically correct, and in compliance with the National Health and Medical Research Council (NHMRC) guidelines and the TGA adopted Guidance on Good Clinical Practice. ADMEC/ADHREC is a registered ethics and research committee, provided for in the NHMRC guidelines issued under the National Health and Medical Research Council Act 1992.

FINDING 3: The trials were conducted by AMI according to the ethical and scientific standards required by ADMEC/ADHREC and the NHMRC. Detailed written records were kept during the trials with this information later analysed and the results presented in a report to ADHREC and published in scientific papers, in order to document and allow proper scrutiny of each trial's findings.

FINDING 4: In the first trial, mefloquine (a once weekly taken drug) was used as a control or comparator drug in a double blind randomised trial involving a relatively new and unregistered drug tafenoquine, also taken once weekly. The use of mefloquine, the ADF's second line anti-malarial drug, as a control was necessary and reasonable to scientifically evaluate the safety, tolerability and effectiveness of tafenoquine to the evidentiary level required to support its future use and registration as an anti-malarial drug. There were very few severe adverse events in the control group using mefloquine during the trial (approximately three per cent); and none of these involved serious adverse neuropsychiatric side effects.
FINDING 5: There was a need and impetus to examine new anti-malarial medications due to the deadly threat of malaria, and the significant number of cases in East Timor among INTERFET troops. The evidence that tafenoquine, a new drug under development: (1) was an effective and safe anti-malarial in eradication and prevention studies overseas and that the risks to the safety and wellbeing of trial participants was very low; (2) offered a once a week alternative to the daily taken doxycycline, potentially providing for better compliance and durability in the field environment; and (3) was believed to have a better side effect profile than mefloquine; provided justification that there were benefits (with a very low risk) in trialling tafenoquine.

FINDING 6: Tafenoquine was found to be safe and effective both in preventing malaria in the high risk malaria area in East Timor, and in the eradication phase upon return to Australia. Tafenoquine is yet to be registered with the TGA, but this is not of itself a valid basis to claim the trial was unnecessary or failed to provide any benefit to soldiers and advancements in the treatment of malaria, as there is clear evidence to the contrary.

FINDING 7: The second trial involved comparing the side effects and effectiveness of mefloquine (Defence's then second line anti-malarial medication) with doxycycline (the first line anti-malarial) under typical field conditions for six months.

FINDING 8: Following the 1999 INTERFET experience with malaria in East Timor, there was a need to evaluate Defence’s existing anti-malarial options against the daily doxycycline medication. The preference by command for a weekly-taken drug, the advantages in compliance, the lack of any significant long term studies of mefloquine in an operational field setting, and the need to test whether known neuropsychiatric (as opposed to neurotoxic) side effects would impact on the operational effectiveness of Australian soldiers, together amounted to a reasonable justification for the conduct of the trial of mefloquine, an already approved and registered anti-malarial drug.

FINDING 9: The claim there was no beneficial outcome from the trial because there was no change in Defence policy, with mefloquine remaining the second line anti-malarial, is rejected. A study of sufficient numbers under field conditions over six months was required to make an informed decision on the future use of mefloquine. The trial was appropriately conducted taking into account the TGA approved product information concerning the very low potential risks involved (See Direction 2 for discussion of mefloquine side effects).

FINDING 10: Mefloquine was found to be effective, safe, tolerable, and comparable to doxycycline. The overall number and type of adverse side effects of mefloquine were found to be similar to doxycycline. The percentage of severe adverse effects in both groups was also similar, except three soldiers (two resulting from undisclosed medical conditions) from over 1100 taking mefloquine who suffered serious neuropsychiatric side effects.

FINDING 11: The medical support provided to the participants before, during and following the two trials was appropriate. There is no evidence any medical issue at the time was not followed up with appropriate and proper medical care.

FINDING 12: The anti-malarial drug trials were conducted ethically and lawfully by the AMI, in accordance with the National Guidelines issued by the NHMRC and the TGA. In the circumstances at the time, the use of the anti-malarial drugs tafenoquine and mefloquine was justified, reasonable
and consistent with relevant health policy and guidance. (See Direction 2 for further discussion on informed consent).

RECOMMENDATION 1: Joint Health Command consider a mechanism to ascertain whether any other participants in the 2000 to 2002 AMI trials who took mefloquine (approximately 1309) may have had any history of a health condition, which would have been a contraindication to mefloquine use. This would ensure that any previous health condition inconsistent with the prescription of mefloquine is identified, and where necessary possible treatment provided through Department of Veterans’ Affairs (DVA) or Defence.

RECOMMENDATION 2: In future medical trials involving Defence personnel, trial investigators be given access to the Defence eHealth System to enable any relevant medical history of contraindicators to be identified at the time of obtaining a Defence member’s consent to participate in the trial.

DIRECTION 2:

Examine the allegation that Defence members were compelled to take mefloquine during the period 2000-2002 and, if so, determine what was said to those Defence members about this compulsion; who said it; what these Defence members understood about the possible side effects of Mefloquine; and whether this compulsion was reasonable in the circumstances and properly authorised.

FINDING 13: In compliance with NHMRC guidelines, participants in the 2000 to 2002 anti-malarial drug trials conducted by AMI were required to voluntarily confirm their willingness to participate in the trial, that is, exercise a voluntary choice, after having been informed at their level of comprehension of relevant aspects of the trial including the risks and discomforts (side effects) associated with taking the drugs. There were not to be any adverse consequences for failing to participate in the trial, including a threat of non-deployment to East Timor.

FINDING 14: Participants in the 1 RAR tafenoquine/mefloquine anti-malarial drug trial undertook a comprehensive three phase medical briefing process culminating in a witnessed consent form being signed before a medical officer. This process ensured that participants were aware of the potential side effects of both drugs and that the trial was a voluntary trial, without detriment to deployment, and they could withdraw at any time.

FINDING 15: Most of the 14 witnesses interviewed in the 1 RAR trial had a limited and vague memory of the informed consent process. Nearly all accept that the medical briefings dealt with the potential side effects of both drugs and that the trial was voluntary. Most witnesses recall that they were told, or believed, that both drugs were safe. Two witnesses, both with a good memory of the consent process, confirm the evidence provided by the principal medical investigator of the trial process, including the explanation of potential side effects and the voluntary nature of the trial.
FINDING 16: The focus of the AMI investigators in the 1 RAR trial was on the experimental drug tafenoquine. The known potential side effects of tafenoquine were properly disclosed to trial participants. No credible evidence was provided that in 2000 tafenoquine was known to potentially cause permanent neurotoxic or other permanent side effects.

FINDING 17: Mefloquine (brand name Lariam) is a registered drug in Australia and has approved written product information and consumer medicine information (CMI). The trial consent form did not include every possible mild side effect of mefloquine listed in the 1998 Lariam CMI, but did disclose two of the three serious, but rare, side effects listed in the CMI, namely anxiety and depression (but not seizure).

FINDING 18: The trial consent form statement that the likelihood of anxiety or depression was considered rare was consistent with the 1998 Lariam CMI, which was ordinarily given to individuals prescribed mefloquine. The failure to list seizures as a rare serious side effect and every one of the many mild side effects of mefloquine contained in the CMI, did not of itself invalidate the informed consent process.

FINDING 19: The consent form and the medical briefings provided to trial participants were not inconsistent with the information contained in the 1998 CMI. In the context of a trial of an experimental drug (tafenoquine), using a registered drug (Lariam - mefloquine) as a control, the consent form contained sufficient relevant information of the potential side effects of mefloquine in a form comprehensible to trial participants, so as to allow them to make an informed decision whether or not to participate in the trial.

FINDING 20: The AMI investigators did not act unethically or unreasonably by not disclosing to trial participants 'mefloquine neurotoxicity' (permanent brain or Central Nervous System injury) as a foreseeable likely side effect of taking mefloquine. The trial consent form was consistent with the 1998 Lariam product and consumer medicine information forms, which did not recognise and include mefloquine neurotoxicity as a possible side effect of mefloquine use. Defence health authorities and the AMI investigators also did not recognise or accept 'mefloquine neurotoxicity' as a possible side effect of taking mefloquine.

FINDING 21: 1 RAR trial participants were appropriately informed by the medical investigators, in a manner comprehensible to them, of the potential side effects of both tafenoquine and mefloquine, and understood that participation in the trial was voluntary without detriment to deployment or future career and they could withdraw any time during the trial.

FINDING 22: CO 1 RAR was focused on taking all necessary precautions to prevent 1 RAR soldiers contracting malaria. Consequently, he addressed the battalion in detail about the malaria issue, and in doing so actively sought to encourage participation in the voluntary drug trial, which he fully supported, was participating in, and believed would assist in the prevention of malaria in the unit.

FINDING 23: The evidence of the six witnesses identified by MAJ McCarthy, with slight variations, was that CO 1 RAR (then-LTCOL John Caligari) said words to the effect if soldiers did not participate in the voluntary trial, they would not deploy. While none of the six witnesses could remember the specific words used, the message to them was clear that it was a requirement to participate in the trial in order to deploy. All six witnesses believe they did not misinterpret
encouragement or an expectation by the CO of participation as a direction or threat that non-participation would result in non-deployment.

FINDING 24: All of the six witnesses identified by MAJ McCarthy 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. However, the witnesses’ overall memories of events 16 years ago surrounding the anti-malarial drug trial, which was conducted during a busy pre-deployment phase, are generally poor and lack detail.

FINDING 25: The suggestion by two witnesses that CO 1 RAR referred to, or may have considered, those not participating in the trials as an administrative or logistic problem, is not supported by the evidence, as there were 400 members of the battalion group who did not participate in the trial.

FINDING 26: Evidence received from eight witnesses who held key command appointments within the battalion was that the trial was voluntary, and none of those eight 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.

FINDING 27: The former 1 RAR provided credible evidence of a strong recollection of the CO’s endorsement of the trial, but no recollection of the CO saying words to the effect, that although the trial was voluntary, if you do not participate you will not deploy. His opinion that some soldiers would have been influenced or encouraged by the CO’s words and others may have felt more than encouragement to participate in the trial, is a reasonable and likely reflection of actual events.

FINDING 28: The former 1 RAR provided credible evidence he definitely remembered the CO saying the trial was voluntary and logically arguing the case for the value of the trial to the unit and to Defence into the future. He did not remember the CO saying words to the effect that if you do not volunteer for the trial then you would not deploy. The CO clearly encouraged participation in the trial, but his words could not be interpreted as a direction.

FINDING 29: CO 1 RAR addressed the battalion about the trial and encouraged them to participate following a conversation with the principal medical investigator resulting in him (the CO) believing that without his support for the trial there may not be sufficient participation.

FINDING 30: CO 1 RAR did not need to threaten soldiers with non-deployment if they did not participate in the trial, as by strongly supporting it and telling them that he was volunteering, he would achieve his aim of ensuring sufficient participation in the trial by 1 RAR soldiers.

FINDING 31: The alleged blatant and contradictory words by CO 1 RAR to the effect that although the trial was voluntary, if soldiers did not participate they would not deploy, would likely have resulted in the matter being raised with him by the command team, and perhaps being brought to the knowledge of those in authority at the time. The fact this did not occur is supportive of LTGEN Caligari’s adamant denial that he did not make the alleged comments threatening soldiers with non-deployment.
FINDING 32: There was strong encouragement to participate in the trial from CO 1 RAR, and the benefits of the trial were promoted by the AMI medical investigators. This likely led to an expectation by command and soldiers themselves that everyone would participate in the trial. It did not occur to most soldiers not to participate. A decision whether or not to participate in the trial was not a significant issue to them; rather, that decision was just another tick in the pre-deployment list of things to be completed.

FINDING 33: No witness could remember the actual words CO 1 RAR is alleged to have said, but rather the ‘effect’ of what he said. Given the intensity of a pre-deployment environment, it is possible some of those present for the CO’s address, including the six witnesses identified by MAJ McCarthy, 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; or alternatively, as an expectation that they were required to participate as part of the deployment.

FINDING 34: Defence members were not compelled to take mefloquine or tafenoquine during the 1 RAR anti-malarial drug trial. There is differing but credible evidence provided by the six witnesses identified by MAJ McCarthy, and the former command group officers and LTGEN Caligari concerning voluntary participation in the trial. The sufficiency and quality of the evidence does not satisfy the required standard of proof to make an adverse finding that the CO used the alleged words (or a similar threat or direction) to the effect that participation in the trial was required in order to deploy to East Timor.

FINDING 35: MAJ McCarthy’s allegation, that in an address to the battalion concerning the anti-malarial drug trial, CO 1 RAR indicated that those who did not volunteer to participate in the trial would be excluded from the deployment, is not substantiated.

RECOMMENDATION 3: The ready acceptance by soldiers of advice or encouragement provided to them by military persons in authority, combined with a potential belief that participation in the trial was expected is an issue worthy of further consideration in the conduct of any future medical trials, particularly in the context of a pre-deployment for an overseas operation.

FINDING 36: Participants in the 4 RAR and 2 RAR mefloquine anti-malarial drug trials received a comprehensive medical briefing, during which they were informed of the side effects of mefloquine, that the trial was completely voluntary, and non-participation would have no effect on deployment or career. These aspects were reinforced at individual doctor/participant consultations when mefloquine was prescribed to the soldiers taking part in the trial. After the loading dose was administered in Australia and prior to deployment, the soldier had a further opportunity to discuss any side effects with a medical officer and to withdraw from the trial.

FINDING 37: Mefloquine is an approved and registered drug in Australia. The information provided in the 4 RAR and 2 RAR trial medical briefings and consent form concerning the potential side effects of mefloquine was comprehensive going beyond that contained in the 1998 Lariam (mefloquine) consumer medicine information normally provided to patients on prescription, and was consistent with the more detailed 1998 Lariam product information. The briefings and consent form provided sufficient relevant information in a form comprehensible to participants, to allow them to make an informed decision whether or not to participate in the trial.
FINDING 38: The AMI investigators in the 4 RAR and 2 RAR trials did not act unethically or unreasonably by not disclosing to trial participants ‘mefloquine neurotoxicity’ (permanent brain or Central Nervous System injury) as a foreseeable likely side effect of taking mefloquine. The trial consent form was consistent with the 1998 Lariam product and consumer medicine information forms, which do not recognise and include mefloquine neurotoxicity as a possible side effect of mefloquine use. Defence health authorities and the AMI investigators also did not recognise or accept ‘mefloquine neurotoxicity’ as a possible side effect of taking mefloquine.

FINDING 39: Participation in the 2 RAR anti-malarial drug trial was voluntary, soldiers were aware that it was and they made an informed decision whether to participate or not. There is no credible evidence of any coercion of soldiers by the CO or others in command to participate in the trial. While there may have been rumours of coercion and encouragement to participate, this did not invalidate the informed consent process.

FINDING 40: No evidence was provided that 2 RAR soldiers were informed that mefloquine was the only drug available.

FINDING 41: One former member of 4 RAR submitted a separate complaint to IGADF that his consent to participate in the 4 RAR mefloquine drug trial was unreasonably and unfairly obtained. The allegation was that he had been compelled to sign the trial consent form in the field in almost dark conditions where he could not read it, and therefore did not know of the risks associated with taking mefloquine. In relation to his complaint:

a. It is likely that the former soldier was provided with sufficient information about the voluntary nature of the 4 RAR trial and the potential side effects of mefloquine during the medical briefings, to allow him to make an informed decision whether to participate or not. The voluntary nature of the trial and the potential side effects would have been reinforced at the mandatory doctor/participant consultation where mefloquine was prescribed to him.

b. The former soldier’s comment he could not believe he was being asked to sign a consent form in the dark, uninformed about the trial and the side effects of mefloquine suggesting this was the first time he knew that it was a real trial, is not credible, given he accepts he would have received a detailed medical briefing.

c. The former soldier’s consent to participate in the 4 RAR mefloquine drug trial was not unreasonably and unfairly obtained. The trial process was conducted in an appropriate manner to ensure the soldier’s decision to participate (by signing the form), and to continue to participate after being prescribed mefloquine was based on informed consent. That he may have received the consent form in the dark and could not read it, or chose not to read it and sign it anyway, had no impact on the information he would have already received.

FINDING 42: There is evidence that 4 RAR and 2 RAR soldiers did not see the drug trials as a significant event, rather it was one of the many pre-deployment matters that had to be completed in order to deploy; and they automatically decided to participate in the trial regardless of the informed consent process.
FINDING 43: Soldiers were not compelled or coerced by command to participate in the 4 RAR and 2 RAR anti-malarial drug trials and to take mefloquine.

FINDING 44: 4 RAR and 2 RAR trial participants were appropriately informed by the medical investigators, in a manner comprehensible to them, of the potential side effects of mefloquine, and understood that participation in the trial was voluntary without detriment to deployment or future career and they could withdraw any time during the trial.

DIRECTION 3

Examine MAJ McCarthy’s allegation that he was threatened with disciplinary action for expressing concern for individuals allegedly affected by mefloquine and, if so, what was said; who said it and whether this was fair and reasonable in the circumstance.

FINDING 45: Between 27 January 2015 and 03 February 2015, MAJ McCarthy had a telephone conversation and an email exchange resulting in a disagreement concerning the permanent effects of mefloquine and the provision of appropriate care for ADF personnel affected by 'mefloquine neurotoxicity'.

FINDING 46: On 15 March 2015 MAJ McCarthy posted comments on Facebook about the Surgeon General ADF (SGADF) and command of an ADF medical system that was criminally negligent in relation to the use of mefloquine and veteran's mental health, and covered up the truth about the effect of the drug. He also posted an official briefing document on mefloquine.

FINDING 47: On 17 March 2015 MAJ McCarthy advised Joint Health Command he had posted his email exchange with on his Facebook page with added explanatory comments about accusing him, amongst other things, of covering up and lying to senior officers about the effects of mefloquine, and conducting an infamous drug trial which poisoned 1100 diggers with a neurotoxicant causing them permanent brain injuries.

FINDING 48: MAJ McCarthy was identifiable from his publicly accessible Facebook account as a member of the Army. The comments on Facebook concerning and the SGADF could reasonably be considered as inappropriate, unacceptable and/or insubordinate, and likely to undermine or prejudice Defence’s reputation, thereby contravening Defence social media and public comment policy.

FINDING 49: The posting of official documentation, including the email exchange with on Facebook contravened the Defence policy on the dissemination of official information by Defence personnel on social media.

FINDING 50: On 26 March 2015 MAJ McCarthy was formally counselled by his Commanding Officer about Defence policy on public comment, dissemination of official information and use of social media policy, and a Record of Conversation made. The formal counselling was instigated by Army Headquarters as a result of the inappropriate comments made on Facebook by MAJ McCarthy concerning and the SGADF. During that counselling MAJ McCarthy was advised that failure to comply with Defence policy may result in discipline or administrative action being taken against him.
FINDING 51: There is no evidence to support MAJ McCarthy’s claim the threatened disciplinary action (made during the formal counselling on 26 March 2015) was instigated by [redacted] as a result of their email exchange and telephone conversation in early February 2015, and their disagreement over the provision of appropriate care for personnel affected by mefloquine neurotoxicity.

FINDING 52: MAJ McCarthy was not threatened with disciplinary action on 26 March 2015 for publicly expressing concern for individuals allegedly affected by mefloquine; rather he was informed he could continue to use Facebook to pursue his interest about raising awareness about the risks associated with mefloquine, as long as he did not post information that could be considered prejudicial to his position as an officer in the ADF.

FINDING 53: On 24 August 2015, MAJ McCarthy was asked by his CO whether he had been involved in writing an Australian newspaper article (published that day) about the conduct of unethical anti-malarial drug trials by the ADF. At the same time MAJ McCarthy was reminded by his CO of their previous discussions about speaking to the media on the broader mefloquine issue. The CO accepted MAJ McCarthy’s explanation he had not spoken to the media and the newspaper article was quoting from his written submission in July 2015 to the Senate Inquiry into the mental health of ADF personnel.

FINDING 54: The Vice Chief of the Defence Force (VCDF) ‘on the record’ response of 24 August 2015 did not focus on MAJ McCarthy and did not personally attack his credibility, but sought to address and to correct claims and allegations in the Australian newspaper article Defence considered were inaccurate and unsubstantiated, particularly those about the unethical conduct of the anti-malarial drug trials. The ‘on the record’ response was not intended to intimidate MAJ McCarthy in order to dissuade him from giving evidence before the Senate Inquiry into the mental health of ADF personnel. MAJ McCarthy was not dissuaded from appearing before the Senate Inquiry and giving his evidence.

FINDING 55: MAJ McCarthy’s belief the VCDF ‘on the record’ response was a direct attack on his credibility is not a credible and reasonable inference to be drawn from the evidence.

FINDING 56: The CO’s reminder on 24 August 2015 about speaking to the media was initially not regarded by MAJ McCarthy as an improper threat of disciplinary action. When MAJ McCarthy later became aware of VCDF’s ‘on the record’ response to the Australian newspaper article, he formed the view the CO’s reminder was a command directed threat of disciplinary action and part of an orchestrated act of intimidation against him because he was about to appear before a Senate Inquiry to give evidence about the ADF’s use of mefloquine.

FINDING 57: The CO was acting of his own volition, and not at the direction of command, in raising the writing of the newspaper article with MAJ McCarthy on 24 August 2015. The reminder to MAJ McCarthy about the limitations on speaking to the media about mefloquine was not an improper threat of disciplinary action.

FINDING 58: MAJ McCarthy’s allegation of intimidation by VCDF and his CO, comprising a public attack on his credibility and a threat of disciplinary action, orchestrated to dissuade him from giving evidence about the use of mefloquine in the ADF at the Senate Inquiry into the mental health of ADF personnel, is not substantiated.
FINDING 59: In the period from September 2015 to February 2016 there is no evidence MAJ McCarthy was threatened with disciplinary action for publicly expressing concerns about mefloquine. Rather, it is evident MAJ McCarthy was allowed to maintain a high profile in mainstream media with a number of newspapers articles featuring his experiences with mefloquine and his concerns about its permanent long term effect on Defence members.

FINDING 60: On 03 February 2016, MAJ McCarthy was counselled by his CO about the posting (tweeting) in late December 2015 and January 2016 of inappropriate comments about the former Chief of Army and the Prime Minister on a twitter account, titled Stuart McCarthy@StuartMcCarthy, which included profile photos of MAJ McCarthy in Army uniform. MAJ McCarthy did not deny or admit to making those comments, or that the twitter account belonged to him. Given the identifying information associated with the Twitter account and in the absence of a denial by MAJ McCarthy as to ownership of the account, the Inquiry is satisfied the twitter account belonged to MAJ McCarthy, and he posted the inappropriate tweets in late December 2015 and January 2016.

FINDING 61: MAJ McCarthy's subsequent complaint of intimidation and harassment against his CO and Chief of Staff of HQ 2 Div for seeking to conduct a further interview with him about those social media comments was resolved when MAJ McCarthy was provided with legal advice and became aware that the purpose of the direction was to deal with further administrative matters and to conduct a Defence Force Discipline Act (DFDA) investigation (not an administrative) interview with him about his social media comments. The direction to arrange an appointment with his CO for an interview was legitimate and was not intimidation or harassment because the CO had previously discussed the matter with him.

FINDING 62: A disciplinary investigation under the DFDA was conducted into MAJ McCarthy's alleged breach of Defence public comment and social media policy for the posting of derogatory comments about the former Chief of Army and the Prime Minister (and others). Following legal advice, MAJ McCarthy declined to answer questions at interview, and ultimately DFDA action was not proceeded with. The instigation of the disciplinary investigation was appropriate (fair and reasonable), particularly given MAJ McCarthy's previous formal counselling on the matter.

FINDING 63: The conduct of the DFDA investigation was not an abuse of power to harass or intimidate MAJ McCarthy for publicly commenting on the effects of mefloquine on Defence members, but was initiated as a result of inappropriate comments about individuals on public social media.

FINDING 64: MAJ McCarthy was not threatened with disciplinary (or administrative) action for publicly expressing concern for individuals allegedly affected by mefloquine. On four occasions (26 March 2015, 24 August 2015, 03 February 2016 and 24 February 2016) MAJ McCarthy was counselled or reminded of the Defence policy about making public comment as an identifiable Defence member in the media and on social media. The formal counselling sessions with his CO (and the disciplinary investigation) were properly initiated as a result of inappropriate and derogatory comments made by MAJ McCarthy about senior ADF officers and politicians on social media, and not as a result of his public comment and discussion about mefloquine. Defence accepted that MAJ McCarthy would continue to make public comments, which were in potential breach of media policy, and chose to deal with those comments by responding publicly to address any matters he raised.
DIRECTION 4

Determine whether COL Brennan became aware of any adverse effects of mefloquine neurotoxicity on Defence personnel. If yes, did he follow relevant health protocols and notify his chain of command.

FINDING 65: The complaint that the 2010 published study paper on the 2000 to 2001 tafenoquine versus mefloquine drug trial in East Timor, co-authored by COL Brennan, failed to include evidence from a subsequent 2006 animal study that mefloquine had allegedly been found to be neurotoxic, able to cause lasting or permanent brain injury with long term or permanent neuropsychiatric side effects to trial subjects, is not substantiated.

FINDING 66: The purpose of the 2000 to 2001 drug trial was to assess the safety, tolerability and effectiveness of a new unregistered drug, tafenoquine. Mefloquine was used in smaller numbers as a control or comparator. It logically follows that a subsequent study in 2006 concerning mefloquine neurotoxicity (regardless of its validity) is not relevant to, and does not impact on, the 2001 trial findings about tafenoquine. The decision not to include information on mefloquine studies in a trial of tafenoquine was reasonably open to the authors of the study paper.

FINDING 67: There was no information in the consent form in either trial concerning mefloquine neurotoxicity as a potential side effect of mefloquine use. This was consistent with the 1998 Lariam (mefloquine) Product Information and Consumer Medicine Information. These TGA approved documents did not recognise the alleged permanent neurological side effects of mefloquine (mefloquine neurotoxicity), claimed by MAJ McCarthy to have been known or at least foreseeable at the time from earlier studies.

FINDING 68: A claim of fraud (deceptive conduct) or negligence against COL Brennan and the other AMI investigators for failing to include information from earlier research and studies, which allegedly showed the foreseeability of mefloquine neurotoxicity, in the medical briefings and documentation provided to both the tafenoquine and mefloquine trial participants and to ADHREC, is rejected.

FINDING 69: There is no substantive evidence that the side effects of mefloquine as detailed in Ministerial correspondence, VCDF media releases, the Defence Health public website or other documentation, using information provided by COL Brennan is deceptive or misleading. While there may be differences in terminology used to describe the side effects of mefloquine, any inference that this is evidence of deception or a cover up of the alleged true effects of mefloquine by COL Brennan is not substantiated.

FINDING 70: The non-acceptance by COL Brennan of MAJ McCarthy's opinion about mefloquine neurotoxicity, and the decision to only provide information about the side effects of mefloquine consistent with scientific peer reviewed research and TGA accepted product information is not of itself evidence of a cover up or deceptive or misleading conduct, by COL Brennan, as inferred by MAJ McCarthy.
FINDING 71: During the conduct of the 2000 to 2002 AMI anti-malarial drug trials, COL Brennan did not become aware of, nor fail to disclose, any neurotoxic adverse side effects of mefloquine to appropriate authorities or his chain of command. Subsequently, COL Brennan has not engaged in deceptive or misleading conduct to cover-up or hide the true impact of alleged known neurotoxic side effects of mefloquine use (mefloquine neurotoxicity) from senior ADF officers, or the wider ADF and veteran community; and has not deliberately or negligently failed to appropriately disclose evidence of mefloquine neurotoxicity in published research study papers.

FINDING 72: There was no conflict of interest in LTCOL Brennan participating as an investigator in the AMI tafenoquine trial in 2000, involving 1 RAR, when at the same time he held the appointment as the Senior Medical Officer for the 3rd Brigade, responsible for providing medical advice to Commander 3rd Brigade.
INSPECTOR-GENERAL OF THE AUSTRALIAN DEFENCE FORCE
INQUIRY REPORT INTO ISSUES CONCERNING
ANTI-MALARIAL TRIALS OF THE DRUG MEFLOQUINE BETWEEN 2000 AND 2002
INVOLVING AUSTRALIAN DEFENCE MEMBERS DEPLOYING TO EAST TIMOR

Introduction

1. On 07 September 2015, 8224716 Major (MAJ) Stuart McCarthy lodged a wide-ranging submission with the Inspector-General of the Australian Defence Force (IGADF) concerning what he submitted was unethical, unlawful and negligent use by Defence of the anti-malarial drug mefloquine.

Background

2. At the time of his submission, MAJ McCarthy was posted to Headquarters 2nd Division (HQ 2 Div) in Sydney and was on sick leave. He suffers from a serious health condition (a neuropsychiatric illness), which caused by his use of the Defence prescribed anti-malarial drug mefloquine (trade name Lariam) in 2001, while participating in a United Nations (UN) African deployment to Ethiopia and Eritrea. MAJ McCarthy uses the term 'mefloquine neurotoxicity' to describe permanent brain or Central Nervous System (CNS) injury, allegedly caused by mefloquine.

3. In 2001 mefloquine, an Australian approved and registered drug was the second line anti-malarial medication used by the Australian Defence Force (ADF). MAJ McCarthy had previously used doxycycline, the first line anti-malarial medication when deployed to Bougainville in 1999, and because he had experienced some side effects, requested an alternative drug. He was prescribed mefloquine; the (ADF) second line approved anti-malarial medication.

4. In the following years MAJ McCarthy continued to serve and undertook further deployments to Sumatra, Iraq and twice to Afghanistan, the last occurring in 2013. During that period, MAJ McCarthy Although he returned to work in 2015 to his new unit (HQ 2 Div) on a limited basis, a further

5. In 2014 MAJ McCarthy began researching mefloquine as a possible cause of neurotoxicity. He made contact with other ADF users of mefloquine who had through social media, including a Facebook page. In May 2014 he submitted a paper on mefloquine neurotoxicity for publication in the Australian Army Journal which was reviewed by the Army Malarial Institute (AMI), and commented upon by Joint Health Command (JHC). At the time MAJ McCarthy was unaware of review, but sought to make contact with in late January 2015 to discuss the mefloquine issue and
attendance at a conference where the matter had been raised. The subsequent email exchanges and a telephone conversation between the two resulted in differences of opinion on the issue. MAJ McCarthy believes Defence and [redacted] are covering up and downplaying the extent of the effects of mefloquine on Defence members.

6. In July 2015, MAJ McCarthy lodged a submission with The Senate, Foreign Affairs, Defence and Trade References Committee Inquiry into The mental health of Australian Defence Force (ADF) personnel who have returned from combat, peacekeeping or other deployment (Senate Inquiry) concerning mefloquine use in the ADF. MAJ McCarthy’s submission to the Senate Inquiry was titled Neuropsychiatric Illness, Brain Injury, Neurotoxic Drugs and Moral Injury in ADF Veterans. He lodged supplementary submissions to the Senate Inquiry in August and September 2015, alleging the ADF’s unethical and unlawful use of mefloquine including the conduct of trials by the AMI.

7. In his submission to IGADF in September 2015, MAJ McCarthy focuses his formal complaint on [redacted] the then [redacted] at JHC, who he claims is at the forefront of the unethical use by Defence of the anti-malarial drug mefloquine, including his involvement in clinical drug trials and his role in policy making. MAJ McCarthy alleges [redacted] and the ADF have failed to care for ADF personnel affected by mefloquine neurotoxicity, including not agreeing with the establishment of an outreach program for veterans given mefloquine. He also asserts [redacted] has been fraudulent by omitting information in a published research paper on one of the mefloquine trials.

8. Surrounding these allegations, and central to his complaint against [redacted] are MAJ McCarthy’s concerns about the conduct of anti-malarial trials of mefloquine held between 2000 and 2002 involving Defence members deploying to East Timor. MAJ McCarthy makes a number of claims about the trials being ‘unethical’, including the failure of Defence to comply with National Guidelines for their conduct. The breaches of the National Guidelines focused on the compulsion of Defence members to take part in one of the trials as a condition of deployment, and the lack of informed consent by participants in both trials. MAJ McCarthy did not take part in the trials and deployments to East Timor between 2000 and 2002.

9. MAJ McCarthy alleges he has been threatened with disciplinary action by his chain of command for speaking out about mefloquine, expressing concern publicly for individuals allegedly affected by mefloquine, and attempting to highlight the mefloquine issue to the Senate Inquiry and to persons in the Defence hierarchy, including [redacted] In particular, he claims he has been intimidated as a witness to a Parliamentary Inquiry, a claim he has expressed to Senator Andrew Gallacher, the Chair of the Senate Inquiry.

Preliminary assessment and Direction to inquire

10. At a Preliminary Assessment meeting on 07 September 2015, the IGADF determined to inquire only into those specific military justice matters identified in MAJ McCarthy’s submission and directed an Assistant IGADF be appointed for this purpose.

11. On 11 September 2015, IGADF issued a Direction to [redacted] to assist him to inquire into military justice issues relating to clinical trials of anti-malarial drugs (mefloquine and tafenoquine) conducted by the AMI involving Defence members deploying to East Timor during the period 2000 to 2002. The principal focus of the
Inquiry is 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 also examined MAJ McCarthy's allegations he was threatened with disciplinary action and intimidated for speaking out about mefloquine.

12. The Inquiry did not examine the general use of mefloquine, or tafenoquine by Defence members, or the side effects that may be caused by the use of those drugs, as these issues fall outside IGADF's military justice jurisdiction.

INQUIRY AUTHORITY AND METHODOLOGY

Inquiry authority

13. The Inquiry was conducted under the authority of, and in accordance with, Part 7 of the Defence (Inquiry) Regulations 1985. On 09 October 2007, [redacted] was appointed as an Assistant IGADF under regulation 82 of those regulations.

Methodology and evidence

14. The Inquiry procedure for gathering relevant evidence included the conduct of recorded witness interviews and seeking answers to questions by email from persons conducting and participating in the anti-malarial drug trials, an extensive review of the AMI trial file documentation, and the collection of supporting and reference documents. The supporting and reference documents included the National Guidelines, protocols, policy and procedures relating to the conduct of research trials, and the Human Research Ethics Committee approvals relating to the trials.

15. The Directions required consultation with relevant subject matter experts as necessary. Expert evidence was received during the Inquiry from officers involved in the conduct of the anti-malarial drug trials and from JHC. However, the Inquiry did not find the need to obtain expert advice from outside Defence on any of the issues being examined, including those that were the subject of complaint, as these issues generally required an assessment of evidence that did not call for expert opinion. The Inquiry did not examine the side effects that may have been caused by the use of the anti-malarial drugs, in particular mefloquine, which would have required independent expert opinion.

16. Conduct of inquiry. The Inquiry was conducted in private.

Witnesses

17. Following a recorded interview with the complainant, MAJ McCarthy, the Inquiry conducted 21 recorded witness interviews (Taped Record of Interview (TROI)) and received emails and supporting documentation from other personnel.

18. Rights and obligations. All witnesses were provided with a copy, and advised of the IGADF witness rights and obligations (Rights and Obligations of Witnesses Involved in Inspector General Australian Defence Force Inquiries) prior to interview. Additionally, witnesses were given
an extract of the Directions to the Assistants IGADF relevant to the evidence they were being requested to provide.

19. **Confidentiality and immunity.** No person was given any guarantee of confidentiality or guarantee of immunity from prosecution concerning his or her evidence or information provided in the course of the Inquiry.

20. **Privacy notice.** Each witness interviewed sighted a privacy notice (*Privacy Notice to Inquiry Witnesses*) and acknowledged their understanding that information they provided, including personal information and information from sources other than themselves, would be recorded and could be used in an IGADF Inquiry report and subsequently released to a broader audience.

21. **Statements of impartiality.** A statement of impartiality and independence was completed by [insert name] and was provided to the witnesses. No apprehension of actual or perceived bias was raised about the Assistant IGADF, and no witness objected to the Assistant IGADF conducting the Inquiry.

**Standard of proof**

22. The standard of proof adopted for the Inquiry was applied in accordance with both *Briginshaw's* standard and *Sullivan's* case. Wherever a finding was made that could potentially affect a person’s rights, interests or legitimate expectations it was not made lightly and only flows from the consideration of evidence having probative weight.

**Procedural fairness**

23. The draft Inquiry Report did not make any adverse findings against any individuals or comments individuals may consider being critical of their actions.

**Inquiry delay**

24. The Inquiry was delayed as the complainant, MAJ McCarthy, [insert details] in October and November 2015 in South East Queensland. An interview was subsequently conducted with MAJ McCarthy on 07 December 2015, following his return to his unit in Sydney. The Inquiry received evidence from February to late May 2016, with many witness not being identified or coming forward until early May 2016.

**DIRECTIONS**

25. The purpose of the Inquiry is to determine whether there was any substance to the allegations contained in the submission in order to ascertain whether any failures in military justice have occurred. Specifically, the Inquiry is directed to:

a. **DIRECTION 1.** Review the circumstances of the alleged trial use by Defence of mefloquine during the period 2000-2002 and determine, in consultation with relevant subject matter experts, if this use was reasonable and consistent with relevant Health protocols and policies at this time.
b. **DIRECTION 2.** Examine the allegation that Defence members were compelled to take mefloquine during the period 2000-2002 and, if so, determine what was said to those Defence members about this compulsion; who said it; what these Defence members understood about the possible side effects of Mefloquine; and whether this compulsion was reasonable in the circumstances and properly authorised.

c. **DIRECTION 3.** Examine MAJ McCarthy’s allegation that he was threatened with disciplinary action for expressing concern for individuals allegedly affected by mefloquine and, if so, what was said; who said it and whether this was fair and reasonable in the circumstance.

d. **DIRECTION 4.** Determine whether COL Brennan became aware of any adverse affects of mefloquine neurotoxicity on Defence personnel. If yes, did he follow relevant health protocols and notify his chain of command.

**DIRECTION 1:**

Review the circumstances of the alleged trial use by Defence of mefloquine during the period 2000-2002 and determine, in consultation with relevant subject matter experts, if this use was reasonable and consistent with relevant Health protocols and policies at this time.

**Background on malaria**

26. Malaria is a potentially life-threatening disease caused by a parasite that infects a certain type of mosquito that feeds on humans. People who contract malaria are typically very sick with high fevers and flu-like illness. If not promptly treated, the infection may lead to kidney failure, seizures, coma, and death. It was reported that in 2015, there were an estimated 214 million malaria cases and some 438,000 malaria deaths around the world. It is also a disease of great military significance and endemic in much of Australia’s area of military operations.

27. During the ADF’s major conflicts since the First World War, malaria has been a significant and, at times, the main cause of casualties. It is reported that malaria has severely impacted the Australian Army’s combat operations on three occasions: Palestine (1918), New Guinea (1943) and Vietnam (1968). Over these years, an Australian military malaria research group, currently known as the Australian Army Malaria Institute (AMI), has been responsible for developing solutions to deal with the malaria problem faced by soldiers on operations.

28. Today the AMI, located at Gallipoli Barracks in Brisbane, is a world recognised centre for malaria research and training. It continues to be responsible for ensuring that the best possible protection is available to ADF personnel against malaria and other mosquito-borne diseases. As a medical research unit, AMI works to prevent mission failure during deployments of the ADF due to infectious diseases that are spread by insects, such as malaria and dengue. AMI conducts laboratory and clinical medical research to decrease the risk of ADF members becoming ill from such infections. AMI comprises a mixture of civilian and military scientific and medical staff that conducts scientific research independently and in collaboration with a number of other research organisations, including the University of Queensland and the Queensland Institute of Medical Research. It is the World Health Organisation’s Regional Collaborating Centre for the Western Pacific.
29. Illness and death from malaria can usually be prevented by the use of preventive medication, insecticides and protective clothing and equipment. However, soldiers operating in the tropics are unable to completely avoid mosquito bites that may cause malaria; therefore, the protection offered by medication is crucial to preventing the disease. Malaria is a complex disease with different medications being effective for different kinds of parasites. These parasites often develop resistance to medications over time, so new medications need to be continuously developed and tested and are crucial to the prevention and treatment of malaria.

Defence policy on malaria

30. The Australian Defence Health Policy Directive 215 Malaria, details the management of malaria in the ADF and the use of anti-malarial drugs. There is no single medication that is 100 per cent effective in preventing malaria and suitable for everyone. All medications can have side effects but some individuals may also demonstrate intolerance to certain drugs. Anti-malarial medications currently used within the ADF are doxycycline, atovaquone/proguanil (trade name Malarone), mefloquine (trade name Lariam), and primaquine.

31. At the time of the Australian deployment to Bougainville and East Timor in the late 1990s, the ADF’s first line preventative anti-malarial medication was doxycycline, and the second line was mefloquine. This meant mefloquine was prescribed when doxycycline was not suitable for an individual to use (Malarone was not a registered drug at that time). Both doxycycline and mefloquine are approved and registered drugs with mefloquine first being registered in Australia under the Therapeutic Goods Administration (TGA) in 1993. When soldiers redeploy to Australia, they are given primaquine, an anti-malarial medication used to prevent relapses of malaria. Primaquine is taken for 14 days to eradicate or kill any malaria parasites that may be present in the body. Primaquine is not related to mefloquine.

Deployment to East Timor

32. In 1999, the ADF conducted operations in East Timor as part of International Force East Timor (INTERFET). East Timor was, and remains, a high malaria risk area. During the first five months of the operation, 64 Australian soldiers presented with malaria in-country. Most of these soldiers were taking doxycycline for prophylaxis (prevention) against malaria. One of the reasons for a large number of malaria cases was believed to be poor compliance as doxycycline must be taken on a daily basis. This provided the stimulus for Defence to look at other options to improve the protection against malaria for the large number of ADF personnel deploying to East Timor.

33. During 2000 to 2002, the AMI conducted two clinical trials of anti-malarial medication, each involving mefloquine. Three Australian Army battalion groups deploying to East Timor participated in the trials. The first trial held in 2000/2001 concerned the 1st Battalion Royal Australian Regiment (1 RAR) and involved a new drug tafenoquine and the approved ADF second line malarial drug mefloquine as a control or comparative drug. The second trial held in 2001/2002 involved two battalions, 4 RAR and 2 RAR, and assessed mefloquine’s safety and tolerability in comparison to doxycycline, the ADF’s first line anti-malarial medication.

34. MAJ McCarthy alleges these clinical trials were unethical and unlawful because they did not comply with the Australian National Guidelines applicable at the time. The Inquiry examined each trial to determine whether they were properly approved and conducted in accordance with
existing Australian and Defence guidelines and policies, and whether the use of the drugs was reasonable or justified at the time and complied with relevant health requirements. In doing so the specific allegations raised by MAJ McCarthy are addressed.

Human research and approval of Defence clinical trials

35. Defence Instruction (General) Administration 24-3 Conduct of human research, (DI(G) ADMIN 24-3) states that conduct of research involving human subjects in Defence must have authorisation and ethical clearance in certain circumstances. One of the functions of AMI is to conduct human research such as clinical trials of anti-malarial drugs. Where there is potential for the research to infringe human ethics principles, including privacy or safety issues, ethical clearance and approval of the conduct of the trial must be obtained from the Australian Defence Human Research Ethics Committee (ADHREC). ADHREC was known as the Australian Defence Medical Ethics Committee (ADMEC) prior to 2001.

36. The conduct of human research and the role of ethics committees in that process is provided for in the 1999 National Statement on Ethical Conduct in Research Involving Humans (National Guidelines), a series of guidelines issued by the National Health and Medical Research Council (NHMRC) under the National Health and Medical Research Council Act 1992. The National Guidelines incorporate, supplement and in some cases override the Note for Guidance on Good Clinical Practice (1995), an internationally accepted standard for designing, conducting, recording and reporting of clinical trials, which has been adopted in Australia by the TGA.

37. ADHREC is a properly constituted human research and ethics committee registered with the NHMRC. Many of the members have no association with Defence and bring specific expertise to the committee. For example, in 2000 one committee member was a Justice of the Supreme Court of the Australian Capital Territory. In the Defence context, ADHREC provides expert review of research protocols submitted for approval by researchers, to conduct human research on Defence personnel. Prior to the commencement of the anti-malarial drug trials, AMI was required to submit a study protocol for each trial to ADHREC/ADMEC for approval, detailing the purpose of the study, the conduct of the trial and compliance with the National Guidelines.

TAFENOQUINE TRIAL (2000/2001)

Background: stated purpose, justification and benefit

38. The first AMI clinical anti-malarial drug trial was ‘A randomised, double-blind, comparative study to evaluate the safety, tolerability and effectiveness of tafenoquine and mefloquine for the prophylaxis of malaria in non-immune Australian soldiers deployed to East Timor’. A trial protocol was submitted to ADMEC on 18 May 2000 (ADMEC Protocol number 216/00). The objectives of the trial were to obtain safety and tolerability data over a six month period, to determine the weekly chemoprophylactic effectiveness of tafenoquine and mefloquine, and to assess the effectiveness of tafenoquine and primaquine in preventing post-deployment malaria.

39. In ascertaining whether the conduct of the AMI clinical trial was appropriate and complied with the NHMRC National Guidelines and Defence health policy, the Inquiry examined the AMI case file, the trial protocol, the study report/paper, the ADMEC (ADHREC) minutes and approval
correspondence and ADHREC audits of the trial protocol. Interviews were conducted with Professor [Name], Lieutenant Colonel [Name] and Doctor [Name] (the Principal Investigators for the trial), and COL [Name] and BRIG [Name] Senior Medical Officer who were both co-investigators.

40. As discussed previously, the high incidence of malaria during the initial INTERFET deployment to East Timor provided the stimulus to examine new medications for protection against malaria for periods of six months duration. Tafenoquine, a yet to be approved and registered medication in Australia, had been successfully used in 1999 on Australian soldiers at the end of their Bougainville tour as a post exposure prophylactic (eradication and prevention) drug. This involved daily doses of tafenoquine for three days in place of the 14 day standard primaquine eradication course. Tafenoquine was found to be very effective. Further evaluation of tafenoquine as a post exposure prophylactic occurred in East Timor with returning INTERFET troops in 2000. The US Army had also been developing tafenoquine as a new anti-malarial drug, and in the late 1990’s tafenoquine had been used to prevent malaria infection in over 1000 people in Africa and Thailand.

41. These Australian and US studies showed tafenoquine was safe, well-tolerated and effective against malaria. The most common side effects reported were gastrointestinal related and headaches, which resolved quickly. Tafenoquine had not been shown to have any neurotoxic or serious adverse neuropsychiatric side effects, such as anxiety and depression. Neuropsychiatric side effects comprise both neurological and psychiatric effects. Neurological side effects include dizziness or vertigo, tinnitus and loss of balance. Psychiatric side effects include anxiety, depression and psychotic behaviour.

42. As a preventative malarial drug tafenoquine had the advantage of a weekly dose with a long half life (longer lasting), which could improve compliance and protection, and be logistically easier to administer. Tafenoquine is related to primaquine and was described by LTCOL [Name] as a long acting primaquine. To properly test and evaluate tafenoquine and to progress its registration as an approved drug, a ‘double blind randomised controlled trial’ was conducted using tafenoquine and another drug, where both the participants and the medical investigators were unaware of which drug was being taken. The drugs were assigned randomly to participants on a three (tafenoquine) to one (mefloquine) basis. The AMI medical investigators stated a double blind trial provided the ‘greatest strength of evidence’ and is ‘much more powerful in terms of determining whether or not this new drug is safe, effective, and well tolerated’. To support this trial, the alternative drug also needed to be taken on a weekly basis, and as mefloquine was already a registered TGA drug and the ADF’s second line anti-malarial medication, it was the only choice for the weekly control or comparator drug. Despite the similarity in their names tafenoquine is not related to mefloquine and acts quite differently in the body.
43. In summary, tafenoquine offered a once a week dosage alternative to doxycycline (taken daily), making compliance for soldiers in the field easier. Furthermore, tafenoquine was more forgiving than doxycycline if a user missed a scheduled dose due to its longer half life. Tafenoquine was also believed to have a better side effect profile than mefloquine.

**Approval of trial protocol**

44. The AMI protocol for the trial was very detailed, providing background on the malaria problem, an examination of earlier research done on tafenoquine, and covered the rationale, justification, objectives and conduct of the trial. It dealt with matters of ethics, procedure, data evaluation, and gave consideration to the issues of drug side effects and risks to participants. It also included medical follow up, benefits to participants and the informed consent process, including voluntary participation and withdrawal from the trial without detriment to the participants.

45. The trial protocol was approved by ADMEC at a meeting held on 05 June 2000 and the formal approval to conduct the trial was communicated by letter dated 14 June 2000. There were minor amendments made to the protocol over the next few months mainly instigated by the AMI investigators. Approval meant ADMEC was satisfied the protocol for the conduct of the clinical drug trial was ethical and compliant with the 1999 NHMRC National Statement guidelines, and the TGA adopted 1995 Guidance on Good Clinical Practice. A Researcher’s Agreement with ADHREC was signed by both LTCOLs (the Principal Investigators) on 15 June 2000, detailing their responsibilities in relation to the trial.

46. TGA approval was also required to import tafenoquine, an unregistered drug, into Australia in order to commence the trial. Details of the clinical trial were provided to TGA, and once it was satisfied the trial had been approved by an ethics committee (ADMEC), the importation approval for tafenoquine was granted.

47. The trial was sponsored by the US Army Medical Material Development Activity (USAMMDA) as part of the US Army Medical Research and Material Command (USAMRMC) and SmithKline Beecham Pharmaceuticals, United Kingdom (UK). The AMI had an arrangement with USAMMDA who provided materiel support and some funding for the trial. USAMMDA had a co-development arrangement with SmithKline Beecham Pharmaceuticals who manufactured and supplied the new drug which was not available in Australia. There was nothing unusual about this arrangement with the US and it was done to obtain access to tafenoquine. In fact LTCOL, the Principal Investigator, commented that one outcome of the arrangement was the trial protocol had to comply with the strict US requirements and was thus one of the most sophisticated he had seen.

48. At interview, it was put to LTCOL that media reporting, and some participants, had suggested the tafenoquine trial was done at the behest of the US Army and the drug company and it was of no benefit to the participating Australian soldiers who were, in effect, guinea pigs. He absolutely disagreed with that suggestion. The trial was initiated by AMI for the benefit of the ADF; however, he confirmed it was necessary to work with the US Army and the pharmaceutical company to obtain the new drug tafenoquine. At interview, Professor also agreed while the trial would be of potential benefit to the US Army, it was clearly of benefit to Australian troops and it proceeded on that basis.
Conduct of the trial

49. The subject population for the 2000/2001 tafenoquine trial was the 1 RAR Battalion Group which was due to deploy to East Timor in October 2000 for six months (returning in April 2001). The Commanding Officer (CO) at the time, LTCOL, now Lieutenant General Retired (LTGEN, Retd) John Caligari, was initially briefed on the tafenoquine trial by LTCOL evidence to the Inquiry was that the CO was aware of the malaria problems that had occurred with the earlier INTERFET deployment of 2 RAR and was very conscious of preventing a similar malaria outbreak in 1 RAR. The CO agreed to support the trial as he saw the compliance advantages from a command perspective of taking an anti-malarial drug once a week over the daily doxycycline. To undertake the trial, AMI provided three lieutenant colonel ranked investigators, including the and other staff. There was little logistical burden placed on 1 RAR and in fact the AMI teams assisted the Regimental Medical Officer (RMO) with the general pre-deployment medical briefs. LTCOL and other AMI members also deployed to East Timor to oversee the trial and provide medical support to participants.

50. Following the CO's agreement to support the trial, a total of 759 personnel underwent the recruitment process in Townsville, which began in August 2000. This process consisted of three medical briefings, the last involving two participants and an investigator where the consent forms were signed and witnessed. (The format and content of the briefings are discussed in Direction 2 when examining the issues of voluntariness and informed consent). The full consent process was completed by 663 individuals representing a consent rate of 87 per cent. The remainder were recorded as 'unable/unwilling to comply with protocol'. LTCOL indicated this grouping was used to potentially protect individuals from suffering any possible recourse from their decision not to enter the trial. A total of 654 volunteers commenced on the trial medication. The upper limit for enrolment was 660 so 99 per cent of the maximum target was achieved. This allowed for 60 withdrawals without affecting statistical reliability.

51. The double blind trial randomised controlled trial meant neither the AMI investigators nor the participants knew which of the two drugs (tafenoquine or mefloquine) were being taken. As the trial was focused on the new drug tafenoquine, three-quarters of trial participants (492) took tafenoquine and one-quarter took mefloquine (162) as the comparator drug (allocated on a random basis). This provided an effective ratio and minimum numbers to adequately test tafenoquine. A three-day loading dose was administered under supervision in Townsville. At that time, two persons experienced adverse reactions to the loading dose and were removed from the trial. Those who did not wish to, or were unable to participate in the trial, were required to take an anti-malarial in order to deploy to East Timor and that was usually doxycycline.

52. The trial drugs were dispensed weekly to the participants in East Timor using each participant's randomisation number and compliance (the taking of the drug) was recorded in a log. Any problems or adverse side effects were reported to unit medical staff and to AMI investigators in East Timor. Depending on the adverse side effect, the soldier could be removed from the trial by medical staff, or at their own volition, and placed on doxycycline.

53. Medical Support. The trial participants were monitored closely during the trial in East Timor and for six months upon their return to Australia. Monitoring included blood tests to look for malaria and to check general health. A sub-group of 100 people were randomly chosen for more
detailed assessment of their eyes and respiratory function. Former 1 RAR members who were interviewed concerning the voluntary nature of the trial (discussed in Direction 2) indicate, in their opinion, appropriate medical support was provided during the trial and upon return to Australia (for example, Mr and BRIG).

Outcomes from trial

54. There were no diagnoses of malaria made for either drug group during 1 RAR’s deployment, although five cases occurred after discontinuation of medication in Australia. The number of adverse events (side effects) reported was similar in both the tafenoquine (13.4 per cent) and mefloquine groups (11.7 per cent). The most common adverse event reported was gastrointestinal upset, and 12 per cent of both groups reported headaches. The trial paper indicated there were 21 subjects who experienced serious adverse events (18 with tafenoquine). However, no serious adverse neuropsychiatric events (neurological or psychiatric side effects) were recorded for either group. The Inquiry did not analyse and assess the validity of the data concerning adverse events (side effects) for either anti-malarial drug, as this was outside the scope of the Inquiry Directions.

55. In the sub-group of 100 (randomly chosen for more detailed assessment of their eyes and respiratory function), an eye condition (a mild vortex keratopathy—corneal deposits) was seen in most people taking tafenoquine. The participants were generally unaware they had the condition. This resulted in the US Army Research Review Board and ADHREC suspending further testing of tafenoquine. An independent expert ophthalmology board concluded this was a benign condition that did not affect vision and in all reported cases it had resolved completely a year after the medication was stopped. At the end of the assessment/review process all members who were on tafenoquine were advised of this benign condition regardless of whether they were afflicted by it or aware of it, so as to avoid any perception of a cover up of the condition. Following resolution of this issue, the final AMI trial report was completed on 09 December 2004 and provided to ADHREC.

56. Overall the trial found tafenoquine was safe and well tolerated as a malaria prophylaxis and an effective weekly anti-malarial drug that can be used without the need for further medication after leaving an endemic area.

57. Tafenoquine is not a banned drug, but remains unregistered in Australia. After the eye condition was resolved by an expert ophthalmology board, tafenoquine has continued to be used in clinical studies (not in Australia) to gather the necessary information to present to registration authorities, such as the TGA. However, opinion evidence provided to the Inquiry is that registration progress may depend on the pharmaceutical manufacturing company’s priorities, including whether the company requires another anti-malarial drug on the market at this time.

58. Audits. As part of its monitoring process, ADHREC conducts regular audits of approved protocols for human research trials and studies. Audits of the Tafenoquine 216/00 Trial protocol included two in 2001 and a desktop review in 2015. No significant anomalies were found other than one missing consent form in 2001.
MEFLOQUINE TRIAL (2001/2002)

Background: stated purpose, justification and benefit

59. The second AMI clinical anti-malarial drug trial was the ‘Evaluation of Safety and Adverse Effects of Mefloquine in the Prophylaxis of Malaria in Non-Immune Australian Soldiers’ (ADHREC Protocol 249/01). The objective of the trial was primarily to define the safety and tolerability of mefloquine under operational conditions. The secondary objective was to assess the effectiveness of mefloquine under operational conditions. This trial compared the side effects and effectiveness of mefloquine with those of doxycycline under typical field conditions. Both these medications were already registered and in use in Australia across the broader population. The trial population was drawn from 4 RAR and 2 RAR Battalion Groups deploying to East Timor during April to October 2001 and October 2001 to May 2002, respectively.

60. In ascertaining whether the conduct of the AMI clinical trial was appropriate and complied with the NHMRC National Guidelines and Defence health policy, the Inquiry examined the AMI case file, the trial protocol, the trial report/paper, the ADMEC/ADHREC minutes and approval correspondence, and ADHREC audits of the trial protocol. Interviews were conducted with Professor BRIG COL (Principal Investigator for the trial), and LTCOL and Doctor (both co-investigators).

61. As discussed previously, the high incidence of malaria during the earlier 1999 INTERFET deployment to East Timor, provided the stimulus and need to examine new medications for protection against malaria for periods of six months duration. During the first trial of tafenoquine (taken once weekly), where mefloquine was used in smaller numbers as a control or comparator drug, mefloquine was found to be well tolerated and accepted by the soldiers. As a result, there were requests for wider use of a weekly medication from subsequent military units and soldiers being deployed to East Timor. Defence also needed to examine the use of its other registered drugs to improve the protection of ADF personnel against malaria. Mefloquine was the ADF’s second line anti-malarial medication and had the advantage of being taken once weekly, which was preferred by commanders and soldiers in the field environment, and could also potentially lead to better compliance.

62. The Inquiry sought an opinion as to why doxycycline was the ADF’s first line anti-malarial and mefloquine the second line, given mefloquine’s perceived compliance advantages and preference by commanders and soldiers. Evidence was provided that it was partly due to historical reasons as doxycycline was developed and used in Australia before mefloquine and found to be successful. Secondly, the neuropsychiatric side effects of mefloquine for some personnel meant that, on balance, doxycycline was the preferred medication. Mefloquine was also said to have developed an undeserved poor reputation from its use by the US military.

63. An examination of the study paper on the mefloquine trial, indicates that there was some limited data on the safety and tolerability of mefloquine for long-term prevention of malaria in military personnel, but no studies had been carried out on Australian soldiers in field conditions. Studies of other military populations in British, Dutch, Indonesian, Italian and US soldiers had shown mefloquine (taken weekly) to be safe and well tolerated, and have better compliance, than daily anti-malarial medications when used over shorter periods than the typical ADF deployment.
Therefore, in order to evaluate and understand the effects of mefloquine as an appropriate once weekly anti-malarial medication for longer term Australian deployments, further studies needed to be undertaken. Approval was sought by AMI to conduct trials of mefloquine in ADF troops deploying to East Timor as a follow on to the smaller (and insufficient) trial done as part of the tafenoquine trial. Furthermore, although the overall adverse events were similar for those using mefloquine compared with those using doxycycline for malaria prevention, it was considered important to examine whether the drug’s known neuropsychiatric (as opposed to neurotoxic) side effects would impact on operational effectiveness.

64. At interview BRIG succinctly summarised the reasons for the mefloquine trial as follows:

In the background we’d had significant problems with malaria and mefloquine was the preferred agent by our coalition partners, and there was an attraction to having a once weekly medication. Mefloquine had been in our policy for over ten years but because it wasn’t a first line medication we didn’t have a lot of safety tolerability data in uniformed people so it was proposed to conduct a trial. If the outcome of the trial was such it could change policy and Mefloquine could have become our first line agent rather than Doxycycline.

He went on to confirm that as the first trial involved testing tafenoquine with mefloquine used as a control in small numbers, it did not provide sufficient (statistically valid) information to evaluate the use of mefloquine over the six month period.

Approval of protocol and trial

65. There was a significant distinction between the 2001/2002 mefloquine trial and the earlier 2000/2001 tafenoquine trial in that both drugs used in this later trial were already approved and registered medications. Theoretically, following the tafenoquine trial, ADF policy could have been changed and mefloquine (the second line anti-malarial medication) could have been prescribed to most ADF members deploying. However, it was decided by AMI to conduct a clinical trial and obtain the ethical approval such a trial entails. This decision was made because it would give soldiers the choice to participate or not; and also allow a higher level of research through the provision of far more detailed personal information by participants than would normally be provided where the drug was prescribed in the usual manner. As the trial was voluntary, an informed consent process needed to be followed.

66. The trial protocol covered the rationale, justification and objectives of the investigation and provided details on the conduct of the trial. It dealt with matters of ethics, procedure, data evaluation, and gave consideration to the issues of the drug’s side effects and risks to participants. It also included the benefits to participants and the informed consent process, including voluntary participation and withdrawal from the trial without any detriment to the participants.

67. The initial protocol approval was provided by ADHREC on 28 February 2001. Over the next six months, the protocol underwent some minor amendments at the instigation of the principle investigators and to deal with the two separate battalions taking part in the trial, and a change in investigators. A research agreement was completed by the Principal Investigator with ADHREC.
Conduct of trial

68. This trial was carried out on two contingents, the 4 RAR and 2 RAR Battalion Groups who deployed to East Timor from April to October 2001 and October 2001 to May 2002, respectively. To satisfy the request of commanders to have a once weekly anti-malarial drug, an open clinical trial was conducted, where soldiers voluntarily enrolled in the trial to take mefloquine. Those who did not participate were still prescribed an anti-malarial, normally doxycycline unless they were intolerant to that drug where they were prescribed mefloquine. As occurred with the tafenoquine trial, medical briefings were given, culminating in the signing of a consent form. (This is discussed in Direction 2 when examining the issues of voluntariness and informed consent). Over the two contingent groups, 1228 initially enrolled in the trial, 1185 provided consent and 1157 commenced using mefloquine. Almost all the remaining approximately 1000 members of both contingent groups took doxycycline. As part of the trial, the 388 soldiers on doxycycline in the first contingent (4 RAR) were also monitored with the 536 mefloquine users.

69. The trial participants were medically assessed prior to starting the trial, while on deployment and before returning to Australia. During deployment the battalion members were supervised using a log return system recorded by a responsible unit member, such as the platoon sergeant. If participants developed any side effects or experienced any adverse events, they were assessed by medical and nursing officers and the medication ceased if required. Some soldiers were unable to tolerate mefloquine (and doxycycline) and changed medication. Soldiers not reporting side effects were still questioned about such symptoms and blood samples were taken from some trial participants to ensure there were no chemical or blood problems that developed in the absence of other symptoms.

Outcomes from trial

70. The results of the trial are set out in the study research paper titled 'Mefloquine and doxycycline malaria prophylaxis in Australian soldiers in East Timor', published in 2005. In summary, of 1157 soldiers starting on mefloquine, 75 (6.5 per cent) withdrew because of adverse responses (side effects) to the drug. Fifty-seven per cent of soldiers using mefloquine reported at least one adverse event, compared with 56 per cent using doxycycline. The most commonly reported adverse events or side effects of both drugs were sleep disturbance, headaches, tiredness and nausea. There were three serious adverse neuropsychiatric events reported in people taking mefloquine. Two of these individuals had undisclosed medical conditions that would have prevented the prescription of mefloquine if they had been known to medical staff.

71. During the trial period only one soldier developed malaria while in East Timor, becoming infected after switching to doxycycline. Of the 968 soldiers still taking mefloquine at the end of their deployments, 94 per cent indicated they would use mefloquine again. Of the 388 soldiers taking doxycycline deployed with the 4 RAR contingent, 89 per cent indicated they would use doxycycline again. The Inquiry did not analyse and assess the validity of the data concerning adverse events or side effects of either anti-malarial drug, as this was outside the scope of the Inquiry directions.

72. Overall, the trial found mefloquine was effective in preventing malaria and was generally well tolerated; and concluded mefloquine should continue to be used for those who cannot tolerate doxycycline. Follow up monitoring of participants occurred over the weeks to months following
return from East Timor for late malaria infections or additional symptoms. No permanent serious adverse events were noted for any soldier from either battalion group attributable to the use of mefloquine.

73. The Inquiry sought an opinion as to why mefloquine remained as the second line anti-malarial drug to doxycycline following the trial. The short answer provided by BRIG was although the trial was done to gather more evidence on mefloquine to inform a possible decision on a change of policy, the outcome of the trial was such that it was not persuasive enough to change Defence policy. Mefloquine was found to be effective, safe and tolerable, and comparable to doxycycline, but the profile of higher neuropsychiatric side effects (albeit there were only three cases in the trial), and some additional advantages of doxycycline in Australia’s geographical region, meant the evidence was not compelling to change the policy. COL (Principal Investigator for the trial) and now the provided a similar opinion to BRIG. He observed it was a blend of the side effect profile, and the efficacy in the areas the ADF is likely to deploy to and when this is taken into account, the trial did not warrant changing doxycycline as the first line anti-malarial. However, both BRIG and COL indicated this did not mean the mefloquine trial was unnecessary as it provided further information on the long term safety and tolerability of mefloquine in deployment conditions.

74. Audits. As part of its monitoring process ADHREC conducts regular audits of approved protocols for human research trials and studies. Audits of the Mefloquine 249/01 trial protocol included an onsite location review on 04 March 2004, and a desktop review in October 2015. No significant anomalies were found that affected the conduct of the trial.

Analysis and assessment of evidence

75. Mefloquine, an approved and registered anti-malarial drug with the TGA (since 1993), was used by Defence in two clinical studies (field trials) during the period 2000 to 2002. Both trials were conducted by the AMI, a specialist Defence medical research unit, and involved Australian battalion groups deploying to East Timor. In the first trial mefloquine was used as a control or comparator drug in a double blind trial involving tafenoquine, a relatively new and unregistered drug. The trial focused on evaluating the safety, tolerability and effectiveness of the new drug tafenoquine, which like mefloquine, is taken once a week. The second trial primarily involved comparing the safety and tolerability (side effects) of mefloquine with doxycycline (the ADF’s first line anti-malarial medication) under field conditions for six months.

76. The Inquiry assesses the AMI study protocols for the two clinical drug trials were carefully reviewed and approved prior to the trial by the then ADMEC, a committee of impartial experts who are responsible for ensuring these trials were both ethically permissible and scientifically correct. ADMEC/ADHREC, is a registered ethics and research committee provided for in the 1999 National Statement on Ethical Conduct in Research Involving Humans, a series of guidelines issued by the National Health and Medical Research Council (NHMRC) under the National Health and Medical Research Council Act 1992. The Inquiry is satisfied the protocols for the conduct of the clinical trials were compliant with the NHMRC National Statement guidelines, and the TGA adopted Guidance on Good Clinical Practice.
77. The clinical drug trials were conducted by AMI according to the strict ethical and scientific standards required by ADMEC/ADHREC and the NHRMC. Detailed written records were kept during the trials with this information later being analysed. In order to document and allow scrutiny of each trial’s findings, the results were presented in a report to ADHREC and published in medical/scientific journals.

Complaint

78. MAJ McCarthy’s submission to IGADF complains the clinical trials conducted by AMI were unethical and unlawful, because of multiple breaches of the National Guidelines and standards provided for by the National Health and Medical Research Council Act. He also lodged a similar complaint to ADHREC on 30 September 2015, which was responded to on the 29 October 2015. The alleged breaches relevant to the conduct of the trials concern the:

a. voluntary nature of participation,
b. lack of information for informed consent,
c. necessity for the trials, given the risk to the safety and well being of individuals, when there was no beneficial outcome, and
d. lack of medical support provided to trial participants who suffered serious adverse effects.

The first two issues of voluntariness and the provision of information for informed consent raised in the submission are addressed in Direction 2.

Necessity for trials: risk versus benefit

79. The focus of the complaint by MAJ McCarthy over the necessity for, and the benefits of, the clinical trials is on mefloquine, rather than tafenoquine. However, the purpose of, and justification for, the first trial was to evaluate the new unregistered drug, tafenoquine, as a once weekly anti-malarial. Mefloquine was used by necessity in the double blind trial in 25 per cent of the participants as a control or comparator.

80. In light of the evidence concerning the deadly threat of malaria, and the significant number of cases in East Timor in INTERFET troops, the Inquiry accepts there was an impetus and need to examine new anti-malarial medications. The evidence presented to the Inquiry, namely:

a. the emergence of tafenoquine as an effective and safe anti-malarial in the eradication of malaria in Australian troops and in prevention studies overseas;
b. tafenoquine offered a once a week alternative to the daily taken doxycycline, making compliance for soldiers in the field easier, and was more forgiving than doxycycline if a dose was missed; and
c. tafenoquine was believed to have a better side effect profile than mefloquine, particularly as regards the lack of any neurotoxic and neuropsychiatric side effects found in earlier studies;
provided convincing justification there were benefits in trialling tafenoquine and that the risk to the safety and wellbeing of the participants was very low.

81. The outcome of the first trial indicated tafenoquine was safe and effective both in preventing malaria in the high risk malaria area in East Timor, and in the eradication phase upon return to Australia. Accordingly, the fact tafenoquine is yet to be registered with the TGA does not of itself support MAJ McCarthy’s claim that the first trial was unnecessary or failed to provide any benefit to soldiers and any advancement in the treatment of malaria, as the evidence is clearly to the contrary.

82. The Inquiry assesses the use of mefloquine, a registered TGA drug and the ADF’s second line anti-malarial medication, as a control in the first trial was necessary and reasonable, in order to scientifically evaluate the safety, tolerability and effectiveness of tafenoquine to the evidentiary level required to support its future use, and registration, as an anti-malarial drug. There were very few severe adverse events in the control group using mefloquine during the trial (approximately three per cent and slightly less than that for tafenoquine); and none of these events involved severe neuropsychiatric side effects.

83. The second trial involved two registered drugs, mefloquine and doxycycline. There was a clear need to evaluate other anti-malarial options to the daily taken doxycycline medication following the INTERFET experience with malaria in East Timor. The advantages seen by command (and soldiers) in compliance and logistics of a weekly, rather than daily, taken medication, the lack of any significant long term (six month) studies of mefloquine in an operational field setting, and the need to test whether the apparent neuropsychiatric side effects would impact on the operational effectiveness of Australian soldiers, are assessed by the Inquiry as reasonable justification for the conduct of the trial. The Inquiry is satisfied that the trial was undertaken with a possible outcome that mefloquine, with its advantages of being taken once a week, could in the future be used more regularly by the ADF, and not only as the second line anti-malarial when doxycycline was not tolerated.

84. Mefloquine was found to be effective, safe and tolerable, and comparable to doxycycline. During the second trial the overall number and type of adverse side effects of mefloquine were found to be similar to doxycycline. In light of the comparable safety, tolerability and effectiveness findings associated with both drugs, and given the profile of higher neuropsychiatric side effects with mefloquine, the evidence was not compelling to change the policy on the use of mefloquine and doxycycline. The Inquiry rejects the claim there was no beneficial outcome from the trial merely because there was no change in Defence policy with mefloquine remaining the second line anti-malarial. The Inquiry finds in order to make an informed decision on the future use of mefloquine (including an unfavourable decision) a trial of sufficient numbers under field conditions over a six month period was needed and justified.

85. Medical support to trial participants. The Inquiry is satisfied the medical support to the participants before, during and following the two trials was appropriate. Where there was an issue such as the mild vortex keratopathy (corneal deposits in the eye), the subjects were followed up for a year or more to ensure there were no adverse effects. There is no evidence produced that any medical issue at the time was not followed up with appropriate and proper medical care. Evidence from witnesses set out in Direction 2 indicates the medical support and care provided during and
ADDITIONAL MATTER CONCERNING CONDUCT OF TRIALS

following both trials in East Timor and Australia was in their opinion appropriate. MAJ McCarthy’s complaint is focused on the lack of medical care for ADF personnel and veterans many years after the trials concluded for alleged neurotoxic side effects of mefloquine, which is not the subject of this Inquiry.

86. In summary, the evidence gathered and reviewed by the Inquiry indicates both trials were conducted ethically and lawfully by the AMI, in accordance with the National Guidelines issued by NHMRC and the TGA. The manner and use of both drugs in these circumstances was justified, reasonable and consistent with relevant health policy and guidance. There is no evidence that trial participants, who suffered adverse effects during the trials or immediately upon return to Australia, were not provided appropriate medical support and care. (The issues of informed consent and compulsion to take part in the trials are dealt with in Direction 2.)
90. The background provided on the soldier’s participation in the 2 RAR mefloquine trial is that he signed the Information and Consent Form Protocol (Consent Form) on 08 August 2001, which stated, ‘If you have had any anxiety attacks or serious depression in the past you also may not be able to use Mefloquine. If you have experienced this type of reaction ... please discuss this with the study Medical Officer.’ There was no evidence on the medical file that any such discussion with a medical officer occurred. The AMI Case Record Form-MQ001 shows that on 04 September 2001 the soldier was admitted to the mefloquine study, and was prescribed and received the medication (Lariam) after satisfying the admission criteria. These criteria were a series of questions asked of the soldier by the AMI medical officer. Again there is no evidence of a discussion of any history of a health condition, which would be a contraindication for mefloquine use.

91. The Consent Form and the Case Record Form do not show the name of the AMI investigator(s) involved, only that an AMI Investigator has sighted the signed Consent Form, and later that an AMI Investigator (medical officer) prescribed the medication. CJHLTH indicated the AMI Investigators did not have access to the trial participants’ medical documents, and it was standard practice to rely on self reporting and answers to questions asked of participants to determine their suitability for admission to the trial.

92. A pre-deployment medical examination (not seen by the Inquiry) was conducted in October 2001 prior to the soldier’s deployment to East Timor. According to CJHLTH, the medical documentation indicated that the soldier was fit for deployment and would be taking mefloquine. The medical, conducted by the 2 RAR Regimental Medical Officer (RMO), did not refer to the soldier’s past history of depression. CJHLTH expressed the opinion that the RMO would probably have had access to the soldier’s full medical records at that time.

93. The subsequent medical file documentation is said to reveal the soldier was taken off mefloquine after a few doses by another medical officer due to his reporting of symptoms (different symptoms to the original condition in 2000), and was changed to another anti-malarial medication for the duration of the tour. Approximately two months later the soldier was diagnosed with a recurrence of his original condition.

94. CJHLTH informed the Inquiry that she:

\textit{concluded that his [the soldier] being prescribed mefloquine as part of the trial and could have been prevented in three ways:}

\begin{enumerate}
\item The member could have identified his past medical history to the doctor during the consenting process.
\item The Medical Officer involved in the trial could have checked [the soldier’s] medical record rather than just relying on him to self-report your past history. This was not standard practice but would have added another layer of safety.
\end{enumerate}
c. If [the RMO conducting the pre-deployment medical] had access to his [soldier’s] medical record (which is highly likely) he should have noted the medical history and switched his anti-malarial medication.

95. CJHLTH determined from her desk top review that:

_In summary, while it is hard to judge from this distance, I believe that this was a failure of the medical system in an individual case rather than an issue with the conduct of the trial per se. In my opinion [the RMO’s] assessment was the final opportunity to bring the entire picture together - ie medication and past history … [and this did not occur]._

96. However, CJHLTH went on to state that this situation would be less likely to happen today due to the new Defence eHealth System. This system allows all Defence health practitioners to electronically access records wherever they are in Australia and ‘provides “flags” to notify practitioners of the contraindications of any medications, thereby reducing the risk of practitioners missing a medication contraindication.’ Therefore, an investigator conducting a trial could be given access to participants’ electronic health records as a means to check for any contraindications.

Analysis and assessment of evidence

97. The Inquiry did not gather any evidence on this case, as JHC had already conducted a review, apologised to the soldier and ensured that steps were in place to prevent any future recurrence. However, the Inquiry did examine whether the conduct of the trial in this particular case was compliant with NHRMC guidelines and other relevant Defence policy at the time.

98. The consent process in the mefloquine trials described to the Inquiry by COL one of the principal investigators, relied on self-reporting by participants of any possible ‘contraindications’ to mefloquine use. Following, the medical brief on the trial, the consent form was not required to be witnessed by an AMI investigator. The key consultation was between the AMI investigator and the soldier, where the soldier was admitted to the trial and prescribed the drug. At this stage the informed consent process was reconfirmed, including a further discussion of the potential side effects of the drug and the voluntary nature of the trial. The prescribing doctor did not have the soldier’s medical file and relied on answers to questions directed to the participant and on self-reporting.

99. The Inquiry assesses that the process followed during the AMI trial was accepted as standard practice by AMI and JHC, and was not in breach of NHRMC guidelines or other known Defence health directives or policy. Although, it was ultimately a question of professional practice at the time, the practicalities of a trial involving a large number of participants may not have allowed a detailed review of each hard copy medical file prior to prescribing the drug, even if it had been available.

100. The final pre-deployment medical review of the soldier’s fitness held in October 2001 was a condition of his medical upgrade and was conducted separately from the anti-malarial drug trial. It is also normal routine that a pre-deployment medical is conducted for all soldiers deploying. CJHLTH has concluded that at this stage the medical officer would have had access to the soldier’s medical file and should have been alerted to his previous medical history and switched him to another anti-malarial drug. While this medical review may have been done by a medical officer who was involved with the AMI trial, it was not a part of the trial. Accordingly, the Inquiry concurs with
CJHLTH's view that the failure (if any) was in the medical system in an individual case rather than in the conduct of the anti-malarial drug trial.

101. However, as explained by CJHLTH, reliance on self-reporting and the need to be in possession of hard copy medical files will be reduced with the new electronic medical records management system, the Defence eHealth System, which should alert medical officers to any contraindications to the use of a particular drug, such as mefloquine. The Inquiry recommends that, as a safeguard, any future medical trial involving ADF personnel should ensure that investigators have access to the electronic medical file of participants in order to check their medical history for contraindicators.

102. CJHLTH stated that had indicated that there were other soldiers prescribed mefloquine when they had a past mental health history, which should have prevented such prescription. CJHLTH has requested their names, but, as at the date of this Report, is yet to receive a response from . The Inquiry recommends that consideration be given to putting in place a mechanism to ascertain whether any other participants in the 2000 to 2002 AMI trials who took mefloquine (approximately 1300) may have had any history of a health condition, which would have been a contraindication to mefloquine use. This would ensure that any previous health condition inconsistent with the prescription of mefloquine is identified and, where necessary, treatment be arranged through the Department of Veterans' Affairs (DVA) or Defence.

FINDING 1: Mefloquine is an approved and registered anti-malarial drug with the Therapeutic Goods Administration (TGA), and was used by Defence in two clinical studies (field trials) in the period 2000 to 2002. The trials were conducted by the Army Malaria Institute (AMI), a specialist medical research unit, and involved Australian battalion groups deployed to East Timor.

FINDING 2: The AMI study protocols for the two clinical drug trials were reviewed and approved by the then Australian Defence Medical Ethics Committee (ADMEC), now the Australian Defence Human Research Ethics Committee (ADHREC), a committee of impartial experts responsible for ensuring such trials are both ethically permissible and scientifically correct, and in compliance with the National Health and Medical Research Council (NHMRC) guidelines and the TGA adopted Guidance on Good Clinical Practice. ADMEC/ADHREC is a registered ethics and research committee, provided for in the NHMRC guidelines issued under the National Health and Medical Research Council Act 1992.

FINDING 3: The trials were conducted by AMI according to the ethical and scientific standards required by ADMEC/ADHREC and the NHMRC. Detailed written records were kept during the trials with this information later analysed and the results presented in a report to ADHREC and published in scientific papers, in order to document and allow proper scrutiny of each trial's findings.

FINDING 4: In the first trial, mefloquine (a once weekly taken drug) was used as a control or comparator drug in a double blind randomised trial involving a relatively new and unregistered drug tafenoquine, also taken once weekly. The use of mefloquine, the ADF's second line anti-malarial drug, as a control was necessary and reasonable to scientifically evaluate the safety, tolerability and effectiveness of tafenoquine to the evidentiary level required to support its future use and registration as an anti-malarial drug. There were very few severe adverse events in the
control group using mefloquine during the trial (approximately three per cent); and none of these involved serious adverse neuropsychiatric side effects.

FINDING 5: There was a need and impetus to examine new anti-malarial medications due to the deadly threat of malaria, and the significant number of cases in East Timor among INTERFET troops. The evidence that tafenoquine, a new drug under development: (1) was an effective and safe anti-malarial in eradication and prevention studies overseas and that the risks to the safety and wellbeing of trial participants was very low; (2) offered a once a week alternative to the daily taken doxycycline, potentially providing for better compliance and durability in the field environment; and (3) was believed to have a better side effect profile than mefloquine; provided justification that there were benefits (with a very low risk) in trialling tafenoquine.

FINDING 6: Tafenoquine was found to be safe and effective both in preventing malaria in the high risk malaria area in East Timor, and in the eradication phase upon return to Australia. Tafenoquine is yet to be registered with the TGA, but this is not of itself a valid basis to claim the trial was unnecessary or failed to provide any benefit to soldiers and advancements in the treatment of malaria, as there is clear evidence to the contrary.

FINDING 7: The second trial involved comparing the side effects and effectiveness of mefloquine (Defence's then second line anti-malarial medication) with doxycycline (the first line anti-malarial) under typical field conditions for six months.

FINDING 8: Following the 1999 INTERFET experience with malaria in East Timor, there was a need to evaluate Defence's existing anti-malarial options against the daily doxycycline medication. The preference by command for a weekly-taken drug, the advantages in compliance, the lack of any significant long term studies of mefloquine in an operational field setting, and the need to test whether known neuropsychiatric (as opposed to neurotoxic) side effects would impact on the operational effectiveness of Australian soldiers, together amounted to a reasonable justification for the conduct of the trial of mefloquine, an already approved and registered anti-malarial drug.

FINDING 9: The claim there was no beneficial outcome from the trial because there was no change in Defence policy, with mefloquine remaining the second line anti-malarial, is rejected. A study of sufficient numbers under field conditions over six months was required to make an informed decision on the future use of mefloquine. The trial was appropriately conducted taking into account the TGA approved product information concerning the very low potential risks involved (See Direction 2 for discussion of mefloquine side effects).

FINDING 10: Mefloquine was found to be effective, safe, tolerable, and comparable to doxycycline. The overall number and type of adverse side effects of mefloquine were found to be similar to doxycycline. The percentage of severe adverse effects in both groups was also similar, except three soldiers (two resulting from undisclosed medical conditions) from over 1100 taking mefloquine who suffered serious neuropsychiatric side effects.

FINDING 11: The medical support provided to the participants before, during and following the two trials was appropriate. There is no evidence any medical issue at the time was not followed up with appropriate and proper medical care.
FINDING 12: The anti-malarial drug trials were conducted ethically and lawfully by the AMI, in accordance with the National Guidelines issued by the NHMRC and the TGA. In the circumstances at the time, the use of the anti-malarial drugs tafenoquine and mefloquine was justified, reasonable and consistent with relevant health policy and guidance. (See Direction 2 for further discussion on informed consent)

RECOMMENDATION 1: Joint Health Command consider a mechanism to ascertain whether any other participants in the 2000 to 2002 AMI trials who took mefloquine (approximately 1300) may have had any history of a health condition, which would have been a contraindication to mefloquine use. This would ensure that any previous health condition inconsistent with the prescription of mefloquine is identified, and where necessary possible treatment provided through Department of Veterans’ Affairs (DVA) or Defence.

RECOMMENDATION 2: In future medical trials involving Defence personnel, trial investigators be given access to the Defence eHealth System to enable any relevant medical history of contraindicators to be identified at the time of obtaining a Defence member’s consent to participate in the trial.

DIRECTION 2:

Examine the allegation that Defence members were compelled to take mefloquine during the period 2000-2002 and, if so, determine what was said to those Defence members about this compulsion; who said it; what these Defence members understood about the possible side effects of Mefloquine; and whether this compulsion was reasonable in the circumstances and properly authorised

103. Policy on informed consent. The NHMRC National Guidelines and the TGA adopted Note for Guidance on Good Clinical Practice require that participation in clinical trials be with the informed consent of the participant. This means that the individuals must voluntarily confirm their willingness to participate in the trial (make a voluntary choice), after having been informed at their level of comprehension of relevant aspects of the trial (including purpose, methods, risks, discomforts, and outcomes of research). There must not be any adverse consequences for failing to participate in the trial. Participants must be free at any time to withdraw from the trial, and if there are any consequences that follow they must have been advised of those before giving consent to participate in the trial. Where persons are in an unequal relationship, such as soldiers occupying subordinate positions in a hierarchical structured organisation, additional attention is required by the ethics committee to be satisfied that consent is both adequately informed and voluntary. Refusal to participate must not result in any discrimination against the individual.

104. Complaint. MAJ McCarthy claims, in his submissions to the Senate Inquiry into the mental health of ADF personnel and to IGADF, there was a lack of informed consent by participating soldiers in the AMI conducted anti-malarial drug trials. This is the most significant breach of the NHMRC National Guidelines alleged by MAJ McCarthy. In particular, his submission to the Senate Inquiry states:

Participants were not properly informed of the drug’s toxic effects and the Commanding Officer of at least one of the units involved (who is now a Lieutenant General) directed that any of his subordinates who did not “volunteer” to participate in the trial would be
excluded from the deployment. In effect they were ordered to take a drug that exposed them to permanent neurotoxic brain injury.

105. The focus of MAJ McCarthy’s submission to the Senate Inquiry and to IGADF is on the effects of mefloquine and the failure of AMI to ensure that trial participants were ‘informed of the foreseeable likelihood of permanent brain injury with long term or permanent side effects’ from its use. The Inquiry examined the two aspects of the informed consent process (disclosure of risks and voluntary participation) used in both the tafenoquine and mefloquine trials.

TAFENOQUINE TRIAL

Informed consent

106. The first AMI clinical trial involved the use of tafenoquine, a yet to be registered new drug being developed for the prevention and eradication of malaria; and secondly, mefloquine (trade name Lariam), an already approved and registered drug used as a control in smaller numbers (3:1 ratio). The trial protocol approved by ADMEC (ADHREC) contained detailed information on the studies on tafenoquine and sections on the safety and side effects of both drugs. As the trial involved a new unregistered drug, both the protocol and ADMEC focused on ensuring there was informed consent by the participating soldiers. By way of example, ADMEC required the ‘consent form be reworded to include the … provision that members can withdraw at any time “without detriment” to my career or ongoing medical care.’ ADMEC was ultimately satisfied that the informed consent process was adequate by approving the protocol and the conduct of the trial.

107. The deployment of the 1 RAR Battalion Group to East Timor was from October 2000 to April 2001. In mid 2000 LTCOL the Principal Investigator from AMI, briefed CO 1 RAR (LTCOL Caligari) and his on the concept of the trial. LTCOL indicated that the CO was aware of the malaria problem that 2 RAR had faced in INTERFET in 1999 and did not want his battalion to suffer any malaria cases. LTCOL was able to offer the CO full medical support for the trial and assistance on other medical matters. At the CO’s request, he explained the risk and benefits of the new drug for 1 RAR soldiers, including the potentially better compliance offered by a once weekly dose. The CO did not provide his agreement for the trial to proceed at the initial briefing, but gave his acceptance a few days later through his 2IC, advising that the battalion would support the trial and AMI were free to bring in their team and talk to his soldiers.

Recruitment process and medical briefings

108. After gaining the CO’s permission, the process to recruit participants for the tafenoquine trial began in early August 2000. There were three investigators of lieutenant colonel rank and other AMI staff involved. In summary LTCOL indicated that:

The recruitment process itself was three phased: Bulk briefing / small group presentation of the trial / two [participants] and a senior MO ( ) doing the witnessed consent process. The voluntary nature of the study was emphasised at all of these interactions. I maintain that no-one would have entered the study without being aware that their inclusion was purely voluntary.
109. LTCOL ______ explained the medical briefing process as follows. The first briefing was a normal general deployment medical briefing to platoons or slightly more numbers, where the trial was raised, following which interest could be expressed about participating and consent forms distributed. Subsequently, (and this was generally a number of weeks later) a smaller brief specifically about the trial was given to groups of six up to section size (10), where the trial was talked through and the opportunity given to ask questions. The brief lasted about 20 minutes and at this stage it was made absolutely clear that the trial was voluntary, what the exclusion and inclusion criteria for the trial were, and detailed information on the risks and benefits of the trial was provided.

110. During that smaller group briefing, LTCOL ______ remembers hearing something from the first day of the briefings about soldiers asking whether they had to be on the trial to deploy, as ‘The battalion says we can’t deploy unless we are on the trial.’ He explained to them ‘No, I don’t want all of you, for starters. I just want you to be here if you want to be here.’ LTCOL ______ told the Inquiry the reference to the battalion having said soldiers could not deploy did not refer to the CO but more generally to the hierarchy, such as Senior Non-Commissioned Officers (SNCOs). LTCOL ______ confirmed that these questions only occurred on a few occasions in the early days of the recruitment process that ran for many weeks from August 2000.

111. The final part of the process was the signing of the consent forms, which generally occurred a few days after the smaller group briefings. This consisted of two persons of equal rank witnessing each other’s consent form (previously given out) in the presence of an investigator (doctor), usually LTCOL ______ or LTCOL ______. During the process, the participants were again briefed about the trial, including the risks and the benefits, and further questions could be asked. LTCOL ______ commented that it was not usual practice to have consent forms independently witnessed in such trials, and in the presence of the investigator. This procedure was followed to make sure that every participant was fully informed and aware that the trial was voluntary, and they could withdraw at any time. However, LTCOL ______ noted that despite this process there was often what he termed ‘consent by consensus’, which is common in the military, where ‘sometimes you get an entire infantry section that signs up, and then the next one, none of them will, because they’ve had their own discussions internally. They’ve come up, if you like, with their own corporate solution to what’s going to happen.’

112. There were some soldiers that did not volunteer for the trial. The battalion group was over 1000 in total and while some soldiers were medically excluded (and others who were not deploying for the full six months did not take part), ultimately there was no difficulty in achieving the minimum number of participants required for the trial.

113. LTCOL ______ concluded by stating:

I can categorically say that out of the group that was presented to us, who subsequently went on to be offered the opportunity of being in the trial or not, was that no one left those rooms with any indication that they were anything other than free to choose;[ and] ... every single one of those groups was told that categorically, “You don’t have to be on this trial to deploy”.
If a soldier did not take part in the trial, they still were required to take an anti-malarial if they wanted to deploy. In that case doxycycline (first line) or mefloquine (second line), both TGA registered drugs, would be prescribed in the normal manner. LTCOL indicated that there were a number of soldiers on mefloquine who were not part of the trial.

Consent form

As previously stated, the National Guidelines require medical briefings, including the consent form, to be framed in a manner that is comprehensible by the participants. The format, level and detail of that information impacts on a participant's comprehension and their informed consent.

The documentation provided to participants was a detailed five page information sheet and a one page ‘Informed Written Consent’, which together comprised the ‘consent form’. As discussed in Direction 1, the focus of the trial protocol and the subsequent medical briefings and consent form was on the testing of the new and unregistered drug tafenoquine, to ensure that proper information was provided to inform consent. There is no evidence or complaints that the medical briefings or the consent form did not properly reflect the known risks and discomforts from taking tafenoquine.

Mefloquine was used by the smaller control group in the trial. As a registered drug and Defence's second line anti-malarial medication, the risks and discomforts (side effects) were briefed to the participants in the normal manner and in terms described in the protocol and on the consent form. LTCOL indicated that the information provided was that known at the time, and was drawn from the Product Information for Lariam (mefloquine). He went on to say that:

In 2000, this is about the depth of information that usually would be provided to somebody in a written sense. You would talk about it but essentially you'd go, "Okay, both of these drugs look to be relatively safe..." The reason there's no mention of the psychotic/psychosis ... is essentially because it hadn't reared its ugly head into the product information, or whatever, at that stage.

The Product Information is a summary of the scientific information about a registered medicine (drug), in this case Lariam (mefloquine), which is written by the pharmaceutical company and approved by the TGA. It provides objective information about the quality, safety and effectiveness of the medicine demonstrated from data provided to the TGA by the company, and is intended to assist doctors in prescribing the medicine. Consumer Medicine Information (CMI) is a leaflet that contains information on the safe and effective use of a prescribed medicine, in this case Lariam (mefloquine). It is written by the pharmaceutical company and is required by the TGA to be made available to consumers either in the medicine pack or by another manner that will enable the information to be provided to the persons to whom the medicine is being prescribed or administered.

The Inquiry examined a copy of the 1998 CMI for Lariam (mefloquine), which was applicable in 2000. The Lariam CMI, rather than the Lariam Product Information, reflects the level of information which should be passed to trial participants in a manner that is comprehensible to them. The lengthy list of possible 'mild' side effects contained in the Lariam CMI include nausea, vomiting, diarrhoea and headaches that are listed in the trial consent form, and other mild events such as dizziness, buzzing or ringing in the ears, which are not listed in the consent form. The Lariam CMI states all side effects should immediately be reported to a doctor, which is consistent
with the advice given to trial participants. The Lariam CMI also states serious side effects are considered rare, and lists the two possible serious side effects as 'seizure (fit)' and a 'change in mood', such as depression and anxiety. Seizure was not listed as a possibility in the trial consent form, but it did state, 'mefloquine has also rarely, about one in 10,000, been associated with depression and anxiety.'

120. LTCOL indicated in 2000 rare events such as one in 10 000 may not have been raised, but today he would probably put more information in the consent form and ADHREC would now insist on it.

121. At interview, BRIG, was asked to comment on the adequacy of the consent form in respect of the side effects of mefloquine. He responded:

> When you're consenting someone to take an experimental drug or investigational drug like Tafenoquine [it] is about the Tafenoquine component. There is very little emphasis on the Mefloquine. Now, looking back with hindsight I would have written that differently.

122. While the list of side effects may have been consistent with the known information, BRIG indicated, in hindsight, the trial consent form did not provide 'a very good description' of the rate of depression and anxiety, which are serious adverse side effects. He stated the rate is more frequent than about 1 in 10 000 and is around 1 in 1000, (which is considered 'uncommon' in the 1998 Product Information, rather than 'rarely' as stated in the trial consent form). However, BRIG agreed that the permanent 'neurotoxic' effects claimed by MAJ McCarthy were not known or foreseeable at the time (and they are not referred to in the 1998 Product Information or CMI). He went on to confirm that there were no severe neuropsychiatric effects reported in either group participating in the trial.

123. MAJ McCarthy’s complaint concerning informed consent is premised on trial participants not being informed of the alleged toxic effects of mefloquine, namely, permanent brain injury (mefloquine neurotoxicity). BRIG was asked to comment on the known side effects of mefloquine and mefloquine neurotoxicity. He stated, '...like all medications mefloquine has side effects. These side effects are pretty well known. The only real development is that some of those side effects may now become - the neurological ones might be permanent rarely.' These include 'balance and hearing, tinnitus.' He went on to confirm that there was no evidence of permanent brain damage being caused by mefloquine and 'that it doesn’t cause or trigger PTSD [Post-Traumatic Stress Disorder].'

Voluntary participation

124. The second part of MAJ McCarthy’s complaint about the informed consent process concerns the voluntary nature of the participation in the 1 RAR drug trial. Based on information from former 1 RAR members, he alleges that soldiers were informed by the CO that those who did not “volunteer” to participate in the trial would be excluded from the deployment. On 13 February 2016, MAJ McCarthy provided the Inquiry with a list of over 30 email addresses of former 1 RAR members who he believed could give evidence on this matter. The Inquiry wrote to those addresses and 16 persons replied by email or telephone. Of those, nine were judged to have
potentially relevant and reliable evidence about the voluntary nature of the 1 RAR trial. The Inquiry was able to interview six of those witnesses and their evidence is set out below.

Witnesses identified by MAJ McCarthy

LTCOL

125. LTCOL [redacted] was interviewed on 21 April 2016. LTCOL [redacted] is an Army Reserve (ARES) officer who left the permanent Army in 2014, and is currently employed as a project manager in Canberra. In 2000 he held the rank of major and was in direct support of 1 RAR. LTCOL [redacted] deployed to East Timor as part of the 1 RAR Battalion Group as the Officer Commanding comprising about 20 personnel. He participated in the 1 RAR anti-malarial drug trial taking tafenoquine, and to date has suffered no known side effects. LTCOL [redacted] became aware of the discussion on mefloquine and the East Timor drug trials through media reporting and from Facebook postings and contact with MAJ McCarthy, whom he has known since attending Royal Military College (RMC) Duntroon in 1990. This resulted in LTCOL [redacted] sending a message through Facebook to MAJ McCarthy indicating that ‘LTGEN Caligari was CO 1 RAR at the time and I remember him telling the entire BG that refusal to participate in the trial would mean that you could not deploy.’ The pertinent information from LTCOL [redacted] interview is summarised as following paragraphs.

126. Participation in trial. LTCOL [redacted] believes that he became aware of the anti-malarial drug trial a few months before deployment. As a member of the battalion orders group, he recollects the trial was seen as a positive thing because taking a drug once a week was going to be a lot easier to manage and control. As a commander, then-MAJ [redacted] believed a weekly drug was beneficial to the battalion as there was less chance of missing the medication, as was the case with daily doxycycline and therefore less risk of contracting malaria. He knew it was going to be a blind trial and he did not know which drug he was taking. He knew it was going to be a blind trial and he did not know which drug he was taking. At the time he did not have any concerns with the trial and was happy to participate, and there was an expectation that everybody would be participating.

127. Medical briefings. LTCOL [redacted] recalls there were both group and individual medical briefings conducted. He vaguely remembers a broad description of the side effects of the drugs was provided, but no disclosures of long-term health risks. He could not specifically recall the consent form or whether the investigators said the trial was voluntary. However, after reading the consent form which he had signed, he accepted the verbal briefing may have included similar information about the voluntary nature of the trial, but he could not specifically recall what was said. The general impression he remembers is that there did not appear to be a choice to participate or not, regardless of what was provided in the briefings or written on the consent form.

128. Voluntary participation. LTCOL [redacted] specifically remembers the CO addressing the Battalion at the Other Ranks’ Canteen about the deployment and the drug trial. The ‘message to the battalion group [was] basically participation in this trial is a requirement to deploy. So words to the effect of, “If you’re not going to participate in this trial then you will not deploy.”’ Although he could not remember the exact words, LTCOL [redacted] indicated that it was ‘abundantly clear what the message was. .. It was very - in absolute terms’. He agreed with the suggestion that the CO may have said words to the effect that the trial was voluntary, but he (the CO) was participating as he saw no dangers, ‘as probably something that I’d expect John to say. But I don’t resile from what
I've said'. By this LTCOL meant he was not inferring from those words that participation in the trial was a requirement for deployment, but the message was clear from the other direct words used by the CO to the effect "If you're not going to participate in this trial then you will not deploy." He told the Inquiry his recollection of what was said had not been influenced or prompted by what others may have told him. That is, his recollection was based on his own memory.

129. **Reason for CO's statement.** At the time, LTCOL did not pay much attention to the CO's words or message, and he recalled no objections amongst his team of soldiers about the trial and what the CO had said. LTCOL was happy to participate, as he thought it was a good idea and it was preferable to take a weekly anti-malarial drug. They also had been briefed that the drugs were safe, so regardless of what the CO was saying LTCOL agreed they were all happy to participate in the trial. On reflection, LTCOL indicated that based on command group discussions he was involved in at the time, one of the reasons the CO may have taken his position about participation in the trial was because it would have been 'a massive embuggerance' to have soldiers in the field on different drug taking regimes. 'So what I believe he was attempting to do, ... was to try and create a routine that could best be supported, that could best support the provision of anti-malarial coverage to his people.'

130. LTCOL had great 'trust' in then-LTCOL Caligari and 'admire[d]' him as a CO. He had worked with him closely and said he was 'absolutely' a good CO. In summarising, LTCOL stated: 'I think to be fair to John Caligari he made a command decision about what was going to be the most practical way for his deployed unit to operate and I think certainly my view at the time was that was entirely fair and reasonable.' He went on to say he felt 'no malice towards JCAL [LTGEN John Caligari]' and was 'not let down by [him]', but 'by the greater Defence medical system.' By this he meant that from his reading and research, the medical system should have been aware of the now-claimed long term effects of mefloquine use and have disclosed them. He said, 'I don't think that ... people were sufficiently informed about what the dangers of, the potential impacts of these drugs were.'

**Mr**

131. Mr was interviewed on 04 May 2016. He joined the Army in 1998 and discharged in 2014 at the rank of sergeant. He deployed to East Timor as private soldier with 1 RAR in 2000, and again in 2003. In 2005 Mr corps transferred to and had deployments to Iraq in 2008/2009 and Afghanistan 2010/2011. During the 2000 deployment, he participated in the 1 RAR anti-malarial drug trial taking tafenoquine.

132. In 2015, Mr became aware of the discussion on the anti-malarial drug trials and mefloquine from media reports about MAJ McCarthy. He joined the Facebook groups to keep abreast of what was happening. Mr is suffering from PTSD and depression and was concerned that he may have taken mefloquine and that may have been a contributing factor to his mental health condition. He applied to AMI for his records, which confirmed to his relief, that he had taken tafenoquine. Mr does not believe his taking tafenoquine contributed to his medical issues. By his own admission, Mr memory of events is poor, which he says is caused by his PTSD. Mr remembers very little about the pre-deployment training and the drug trial in 2000.
133. **Medical briefings.** Mr has no memory of the medical briefings, or the consent form process. ‘Prior to deployment, we were getting briefs about everything, as you do, and it’s all just sort of blurred into one’. However, he had no reason to doubt that there would have been medical briefings about the trial and the drug’s side effects, and that from the medical perspective the trials were voluntary.

134. **Voluntary participation.** Mr described CO 1 RAR, LTCOL Caligari, as ‘charismatic’ and ‘good - what you want in a CO. ... He led by example. ... He was always giving rousing speeches in front of the battalion at boozer parades and everything, gave everyone esprit de corps’. The one aspect of the trial Mr says he does remember was the address by the CO about participation in the drug trial, which likely happened on the parade ground. Although he initially believed the address occurred in the few weeks before deployment he later said that it occurred early in the deployment training, around August. Mr recalled the CO saying words to the effect ‘If you don’t volunteer, you’re not going.’ Although he could not remember the specific words, the CO was very blunt and to the point about it, ‘It’s the way he spoke. It was very, “If you don’t take it, you’re not going.”’ He accepted that the CO may have also stated words to the effect that the trial was voluntary, he supported it and was participating, but there was ‘no grey area’ to what he recollects hearing, which was in effect, ‘Take it or don’t go.’ He supported this view with a comment that ‘there was no way that every single soldier would have volunteered if it wasn’t made compulsory’. But Mr also conceded that most soldiers were keen to deploy and willing to accept anything to go, which by implication included participating in the drug trial. At the time he was happy to participate in the trial as he was keen to deploy and he trusted the Army to have done their research and that the drugs were safe.

135. **Reason for CO’s statement.** Mr did not know why the CO would say that the deployment was dependent on participation in the drug trial and such an ‘order’ seemed out of character for him. He speculated that it could have been because there were not sufficient numbers of volunteers, or the CO wanted to impress on the other battalions that 1 RAR was behind the trial of the drug and was not going to lose any soldiers to malaria.

136. Mr stated that his view on what the CO had said was not influenced by speaking with others or by media reports or Facebook. He says that the issue first came to his attention when he read a media article referring to what LTGEN Caligari said about participation in the 1 RAR drug trial being voluntary (August 2015). This triggered his memory about the parade as this was different to what he remembered. While he remembered little about the pre-deployment training, he was confident about his recollection of the direction given by the CO about participation in the trial being a prerequisite for deployment.

**Warrant Officer Class 2 (WO2)**

137. WO2 was interviewed on 09 May 2016 and is currently a serving member posted as the Warrant Officer Hulsworthy. He joined the Army in 1995 and in 2000 was a 1 RAR. Since his first deployment to East Timor, WO2 has deployed to the Solomon Islands, Iraq and East Timor again. He participated in the anti-malarial drug trial, taking tafenoquine.
Whilst in East Timor, W02 suffered some side effects, namely, weird ‘terror’ dreams on the night he took the weekly dmg. On his return to Australia he suffered from mood swings and anger, noticeable to others, which lasted for about a year. When W02 returned from Iraq he suffered similar mood swings and he attributed these to a normal part of being deployed. He occasionally still suffers from those mood swings, but has not sought any medical advice or treatment. In 2015 W02 became aware of the discussion concerning the anti-malarial dmg trials from friends and media reports, and started following MAJ McCarthy’s Facebook postings. He now believes that there may be a connection between tafenoquine and the mood swings that he has suffered from.

Medical briefings. W02 has a vague memory of the medical briefings as one of the many pre-deployment matters. He remembers signing the consent form, but not the process leading up to it. However, he recalls being advised by the medical investigators of some of the information in the consent form, including the side effects, which were described as relatively minor. As set out in the consent form they were told the drugs were safe, and no information was provided on any serious side effects of either drug. He did not recall being told that tafenoquine was an experimental drug and not yet approved. However, when further questioned, W02 did recall the doctors emphasising that the trial was voluntary and that you did not have to participate. There was no pressure from his immediate superiors to participate and he said ‘definitely, I knew it was a voluntary thing.’ In any event, he and everybody else were so keen to deploy they would have accepted anything, short of being told that drug may kill them.

Voluntary participation. W02 described LTCOL Caligari as a ‘good … firm and fair’ CO, agreed that he led by example, and communicated directly and well with his soldiers. He recalls that the CO addressed the unit at the Other Ranks’ Canteen on a regular basis (referred to as ‘the boozers’ parade) and at one of those addresses he talked about the drug trial, which W02 believes was the first time he became aware of the trial. This occurred around the same time of the medical briefings but he is not sure how long before deployment. He said the CO was ‘talking about the trial that the battalion was going to be a part of,… I remember him saying that if you didn’t take part in the trial, he would seriously consider whether he deployed you or not.’ He was sure he remembered the word ‘consider’ was used rather than a blanket denial of deployment, which other witnesses have suggested was said. When questioned further W02 could not think of a reason why the CO would say these words, and then admitted he was not ‘a 100 percent sure’ what words were used. Nevertheless, the effect of what was said clearly meant to him that deployment was dependent on participation in the trial.

WO2 was referred to the press release where the CO indicated during the address to the battalion that he said the trial was voluntary, he supported it and was (himself) participating. He was asked whether these words could have been used as a means of encouragement and leading by example, rather than a direction or threat to participate which he remembers. W02 replied that ‘I remember him saying about him supporting the trial and that he was going to take part in it, and encouraging people to be a part of it. I do remember him saying that, now you’ve said it. However, he did definitely say what I said as well.’ When asked whether what the CO said, be it a direction or encouragement, impacted on his participation in the trial, W02 replied: ‘Well, we were dead keen to go, so I was going to do anything I had to do to go.’ He agreed the trial was one of many pre-deployment events happening and participating in it and the briefings ‘was like another box you had to tick in pre-deployment.’
142. It was put to WO2 [redacted] that the CO might have made other directions at battalion briefings, for example, concerning the making of wills as a pre-deployment requirement. He recalled that the CO said ‘Everyone was to have a will, and everyone was to have body bits insurance, and everyone was to have life insurance’. The relevance of this relates to new evidence given on 04 May 2016 by COL [redacted] a 1 RAR [redacted] during the trial, which is discussed below.

Mr

143. Mr [redacted] was also interviewed on 09 May 2016. He joined the Army in 1995 and served as a rifleman in 1 RAR. In 2000 he was a lance corporal and 2IC of a section in [redacted]. He discharged in 2004 as a corporal, having been returned from Malaysia suffering depression which was later diagnosed as PTSD. He is currently on a Department of Veterans’ Affairs (DVA) pension. Mr [redacted] participated in the 1 RAR anti-malarial drug trial in 2000, taking tafenoquine. In 2015 he became aware of the discussion concerning the anti-malarial drug trials from MAJ McCarthy’s Facebook page and he noticed that other 1 RAR members were posting comments about the trial and the effects on them, which were similar to his own.

144. **Medical briefings.** Mr [redacted] had little to no memory of the pre-deployment trial process, including the medical briefings and the signing process of the consent form. In response, he said that ‘my memory’s not the best. I’ve been on a lot of medication since then.’ Putting events to him, including the detail of the consent form, which he signed, did not assist his memory. He was aware that the trial involved two drugs but did not remember finding out what drug he was on until he applied for his medical documents from AMI.

145. Mr [redacted] suffered side effects from tafenoquine during pre-deployment loading doses of the drug in Australia and then in East Timor, comprising vomiting, diarrhoea, aches and pains, which he was reminded about when he obtained his medical documents. These side effects dissipated over time and when he returned to Australia he did not suffer any further effects, although his wife and friends described him as ‘not the same person’. He recalled when he got home, ‘I was ‘shattered ... suffering severe mood swings, depression and I broke down in 2002 [when in Malaysia at Butterworth] and I haven’t been the same since.’

146. **Voluntary participation.** Mr [redacted] believes he first found out about the trial when the CO addressed the battalion on parade. He does not recall when the parade was, and stated, ‘I can’t remember exact words, but I can remember him saying “Righto, men, we’re going. You’ve got dates. You have been chosen for a new anti-malarial drug trial. You won’t know what you’re on. It’s voluntary however if you don’t take it you don’t deploy.” And I remember within the ranks people were sort of mumbling and talking and laughing about it like. ’Mr [redacted] did not remember the CO saying that he supported the trial and was participating. Despite his admitted poor or no memory of most events surrounding the trial and the pre-deployment phase, Mr [redacted] was ‘100 per cent sure’ the CO said the words he claimed, and his memory is not based on what others have told him or what he may have read on Facebook, but is his own recollection.

147. **Reason for CO’s statement.** Mr [redacted] believed that LTCOL Caligari was a good and fair CO, who communicated well with the troops and led by example. In that context he agreed that saying the trial was voluntary, however if soldiers did not take the drug they would not deploy, was unusual and that is why some soldiers mumbled and laughed when they heard it. He agreed that
what the CO said made no difference to them participating in the trial as they all wanted to deploy and would have taken the drug anyway, unless they were informed that the drug was dangerous or life threatening, which was not the case.

Mr

148. Mr was interviewed on 10 May 2016. He joined the Army in 1990, retired as a Warrant Officer Class 2 in 2010 and now is employed in Townsville. In the early 1990s he served in 1 RAR and deployed to Somalia in 1993. In 2000 Mr was a corporal and a section commander in 1 RAR. He participated in the anti-malarial drug trial, taking tafenoquine, and suffered only one side effect from the medication, namely, the corneal deposits in his eyes which he was unaware of at the time and which dissipated after he stopped taking tafenoquine.

149. In 2015, Mr became aware of the discussion led by MAJ McCarthy concerning the anti-malarial drug trials from being tagged through some of his friends to the Facebook page on the Australian Mefloquine/Tafenoquine group. Mr became interested because he had taken part in the trial, but could not remember which drug he was given. In December 2015 he applied to AMI for his medical records, which confirmed he had taken tafenoquine.

150. Medical briefings. Mr remembered having medical briefings concerning the trial as part of the many pre-deployment briefings that occurred. However, his memory of the content of those briefings was not good. He was aware the trial was a double blind trial using tafenoquine, an experimental drug, and mefloquine which he thought was approved. Mr recalls being told something about possible side effects of the drugs and that, ‘If they made you sick or you had an adverse reaction, you’d be taken off it straight away.’ He agreed the information in the consent form, a copy of which he had obtained from AMI, was consistent with the medical briefings as far as he could remember. In particular, it was clear to him from the medical brief and consent form that participation in the trial was voluntary without detriment to career, including not being deployed. Mr believed there was an advantage in taking a once weekly drug and was happy to participate in the trial.

151. Voluntary participation. Mr believes he first became aware of the anti-malarial trial when the CO addressed the battalion on parade. It was around the same time as the medical briefings in August/September 2000. The brief covered a range of matters concerning the deployment. However, the only thing he remembers is the CO speaking about the drug trial and ‘saying that it is voluntary but if you don’t take it you won’t be deployed to East Timor,’ or ‘it was a voluntary drug but if you don’t take it you won’t deploy.’ Mr told the Inquiry his memories of what the CO said were his own and were not based on what he had read on Facebook. He said: ‘I remember what was said on the parade ground and, yes, that’s definitely what was said.’ Mr did not recall the CO saying that he supported the trial and was participating (as reported in the press release), and was not misinterpreting any words of encouragement, because he did not remember any being said. However, he believed the CO was a good leader, communicated well with the soldiers and led by example. He speculated that the CO would have taken the drug to lead by example, and if the CO ‘thought any of these drugs weren’t safe, I don’t think he’d want us to take them.’
152. **Reason for CO’s statement.** Mr [redacted] remembers the CO’s words because he thought it was strange for the CO to say that the trial was voluntary, and then say that if you do not take the drug you do not deploy. He recalls thinking at the time, ‘That could bite him in the arse one day. Why would he have said that?’ He could not think of any reason why the CO would say the words because everybody wanted to deploy and was going to participate in the trial regardless of what was said. There did not seem to be a problem with soldiers volunteering for the trial. He stated that ‘no one’s going to say, “No, I won’t take that.” ‘ Well, that’s why I thought it was a bit, sort of, strange that he said that.’ At the time he did not consider it a big issue and did not discuss what the CO said with anyone else. Mr [redacted] speculated that the CO said the words simply because ‘he wanted everyone to deploy.’

Mr [redacted]

153. Mr [redacted] was interviewed on 12 May 2016. He joined the Army in 1997, discharged in 2001, and is currently employed as an electrician in [redacted]. In 2000, he served in [redacted] 1 RAR and the then-CPL [redacted] was his section commander. Mr [redacted] participated in the 1 RAR anti-malarial drug trial and was given tafenoquine. He became aware of the discussion concerning the anti-malarial drug trials after being tagged on Facebook through friends. Having read the information provided, in hindsight he now believes that it is a possibility his reoccurring dizzy spells which started about five years ago, may be related to his taking tafenoquine and he would like to know whether this is the case.

154. **Medical briefings.** Mr [redacted] remembers receiving a single medical briefing with about 30 other soldiers. At the briefing it was explained the anti-malarial drug trial was a blind trial involving tafenoquine and mefloquine, which would be taken once weekly. He could not recall whether the side effects of the drugs were explained, but having obtained a copy of the consent form, he accepted the doctors would have passed on the information contained in the form at the briefing. He also agreed it was made clear by the doctors the trial was voluntary and non-participation would not affect deployment. Mr [redacted] recalled there was a meeting to sign the consent form where the AMI expert and perhaps the SMO explained what was in the form. However, he did not remember a separate meeting or briefing to sign the consent form, but rather it may have happened straight after the first briefing of about 30 soldiers, and the witnessing involved the soldier sitting beside you, but he is not sure. Following the medical brief Mr [redacted] had no concerns with participating in the trial, as he believed it was explained the drug was safe with only minor side effects.

155. Following the initial loading dose in Townsville Mr [redacted] had no side effects, but in East Timor he suffered from abdominal pains and gastroenteritis requiring him to twice attend the Regimental Aid Post, a medical aid post. On a handful of other occasions, immediately after taking the weekly pill he was sick. This stopped after a few weeks. At the time, he did not associate his illness with the anti-malarial drugs. Upon his return to Australia, he did report to the medical centre with a sore throat and had to be sedated and put on a drip. Mr [redacted] did not know whether this was caused by the anti-malarial drugs. He was also briefed along with about 50 others about corneal deposits in his eyes caused by tafenoquine that had been observed in tests, which Mr [redacted] was unaware of at the time and which dissipated without permanently affecting him. After going on leave he did not suffer any further side effects that he attributed to tafenoquine. Mr [redacted] was asked whether the medical support provided during the trial, and in Australia, was adequate and commented, ‘I don’t think they could have been any more thorough.’
156. **Voluntary participation.** As was the case for Mr [redacted], Mr [redacted] believes he first became aware of the anti-malarial trial when the CO addressed the battalion on parade, but that it probably occurred before the medical briefings. He also agreed that the CO was a good leader, communicated well with the soldiers and led by example. The CO’s address to the battalion covered a number of matters one of which was the drug trial. Mr [redacted] recalls that the CO said words to the effect:

*Okay, we’re soon to deploy to East Timor. I’ve had people approach me about partaking in an anti-malaria drug. I’ve put my hand up and I’m going to be part of the trial. I believe that, if it’s good enough for me, it’s good enough for you. If anyone objects, I’m going to consider you an administrative problem/issue and you will not be deploying to East Timor.*

He explained, ‘the reason why everyone sort of remembers [and] their ears pricked up is because I remember thinking to myself, “What part of that is volunteer?”’

157. Mr [redacted] agreed that the CO may have said the trial was voluntary, that he supported it and he was participating. But the CO ‘didn’t say you had to participate’ rather, ‘what he’s failing to mention is, he’s threatened non-deployment for anyone who doesn’t participate.’ Mr [redacted] stated he remembered those words because they were unusual and he always thought something would come of it. He denied he may have picked up or adopted the words from what was being said by other people, including Mr [redacted] whom he has spoken to about the matter.

158. **Reason for CO’s statement.** Mr [redacted] was asked why the CO would have threatened non-deployment of non-participants in the trial for being an ‘administrative problem’. (No other witnesses including Mr [redacted] had referred to those words.) He replied that it was a good question, and speculated the CO thought that if it was good enough for him to participate then everyone else was going to, in order to ensure sufficient numbers for the trial. But he acknowledged the issue of numbers was never raised by the CO, and Mr [redacted] was surprised to learn a large number of the battalion group did not participate in the trial for various reasons. When asked how there could be an administrative problem or liability if about 400 of the 1100 soldiers were not participating in the trial, Mr [redacted] responded that this only reinforced his view the CO must have been using this as a threat or a means to ensure sufficient numbers for the trial.

159. Consistent with evidence of other witnesses, Mr [redacted] agreed with the suggestion there was no need to make this threat of non-deployment if you did not participate in the trial. He believed everybody was keen to deploy, and based on the medical information that the drugs were considered safe, and knowing the CO would never promote an unsafe drug, they all would have participated in the trial, regardless of what the CO said.

**Other 1 RAR witnesses**

160. In addition to the witnesses identified by MAJ McCarthy, the Inquiry sought to interview other former 1 RAR members about the conduct of the anti-malarial trial, in particular about their knowledge of the CO’s address to the battalion about the voluntary nature of the trial.
was able to interview or receive written information from eight of those individuals. The relevant evidence from these witnesses is summarised in the following paragraphs.

COL

161. COL [unclear] and in 2000 held the position of 1 RAR at the rank of captain. He was interviewed on 28 April 2016, and indicated his memory of events 15 years ago and in particular the anti-malarial trial was vague. As he did not oversee the trial, the [unclear] had that role. Furthermore, he was one of 100 or more members of 1 RAR who returned to Australia mid-deployment on posting, so did not actually participate in the trial. He was not involved in the medical process for consent, but recalls that LTCOL [unclear] from AMI did undertake briefings. From COL [unclear] perspective the 1 RAR anti-malarial drug trial was voluntary and there was no threat of non-deployment.

162. COL [unclear] described the former CO 1 RAR, LTCOL Caligari, as an exceptional leader with a 'very human style of engagement with people, very open and honest with people, would talk to anybody regardless of rank' [and] 'invested as much time in speaking to groups of soldiers as he did groups of company commanders.' At the time he held regular command group briefings where the drug trial would have been raised, but he does not remember the discussion. The CO commonly addressed the battalion in the Other Ranks' Canteen and on parade. Again he has no specific memory of the CO discussing the drug trial at one of those parades, but has no doubt that he would have. COL [unclear] indicated he became aware of the rumours and allegations made against LTGEN Caligari about what happened on the parade from his job as [unclear].

163. While COL [unclear] could not categorically rule out that the CO may have said words to the effect that, although participation in the anti-malarial drug trial was voluntary, if soldiers did not take part in the trial, they would not deploy, he believed the CO would not make such a comment. He said, 'it gets back to Caligari's command style, you know, he was frank, honest, and raw, but that's not the sort of thing that he - at least from my experience with him, that he would say....he's not a hang threats over people's heads type of guy.' COL [unclear] commented that the CO's explanation to the battalion that he supported the trial and was participating 'was consistent with his character'; [and said by the CO] 'to give them a sense, and not necessarily I don't think to stiff arm them into taking it, but more just to give them a sense that, hey, look, and declaring that up front he's not asking, or that the Defence/Army, is not asking them to consider taking a drug that he wouldn't, that he hasn't decided to take himself.'

164. Furthermore, if the CO did make such a comment, it was something COL [unclear] would definitely remember, and that he and other members of the command team would have challenged the CO about it. He told the Inquiry, 'the relationship that the CO had with the company commanders, which was open and honest both ways, you know, definitely examples of it coming the other way at the CO, that if there were any of those concerns, not just from the company commanders but the RSMs, the CSMs.' His evidence was that their relationship would have allowed such a challenge.

165. COL [unclear] declared he is still friendly with LTGEN Caligari and at a group meeting in Townsville last year the drug trials and MAJ McCarthy's allegations were raised with him, but not discussed in any detail. COL [unclear] denied he was protecting LTGEN Caligari in any way, for example, by not remembering what had happened. He said he understood the gravity of these interviews and would not lie to an IGADF inquiry.
MAJ was interviewed on 03 May 2016, a few days after he had retired from the permanent Army and transferred to the Reserve. Prior to being commissioned, MAJ was the 1 RAR. In 2000 he was the 1 RAR. As was the case with COL MAJ, memory of events of some 15 years ago and the anti-malarial drug trial, as one of many pre-deployment issues, was vague. He too was posted mid-deployment back to Australia and did not participate in the trial. MAJ had no involvement in the trial program.

MAJ believed the trial was voluntary and he did not recall any problems being raised about recruiting participants. The management and compliance advantages to command and to soldiers of taking a once-weekly drug were clear, and the new drugs were the way of the future. Furthermore, he agreed that every soldier was keen to deploy as this was the first deployment for 1 RAR since Somalia in 1993, and this meant soldiers would probably sign up after the medical briefings without much difficulty. He agreed with LTCOL the AMI Principal Investigator’s evidence that the section group (as the smallest team in the battalion) would often make a group decision whether to sign up or not, led by the section commander.

MAJ had no recollection of any address or briefings by the CO to the battalion on the drug trial, but based on his knowledge of the CO he was sure there would have been. He was now aware of the allegations made that participation in the trial was not voluntary, but at the time that issue was never raised at command group meetings or with the battalion that he could recall. MAJ indicated if the CO had said the alleged words to the battalion he would have noted that and raised it with him. Furthermore, MAJ stated, ‘it’s not in the character of the man … He never used that type of language to threaten or force people to do stuff. That’s the issue. It’s just not his nature.’ The CO was described as an ‘excellent leader … who would mix with the troops, talk to the troops, ask their opinion, all that type of stuff. So he was a soldier’s leader’. MAJ also said that the CO led by example, noting that when the battalion was trialling capsicum spray the CO were the first to be exposed to it.

The words LTGEN Caligari said he used in his address to the battalion at the time, namely, that the trial was voluntary, he supported it and was participating, were not recalled by MAJ but he said ‘that’s exactly what he would have said.’ Furthermore, he agreed that the CO would also have been using these words as encouragement to participate. He could not think of a reason why former 1 RAR members would now be saying the CO had made deployment conditional on participation in the trial. MAJ was adamant ‘John Caligari never used that type of language to threaten or force people to do stuff. That’s the issue. It’s just not his nature.’ After being provided with more detailed information on what the various witnesses had said, MAJ reiterated: ‘I mean, from the point of view of John Caligari saying those words, I’ve never ever heard him threaten that type of thing. If it’s voluntary, it’s voluntary and that’s the way he would accept it. It’s uncharacteristic for him if he did say that, but I didn’t hear him say it. I can’t remember being shocked.’ MAJ denied that he was trying to protect LTGEN Caligari by failing to remember what was said.

In response to the comments made by Mr and the views of LTCOL that the CO referred to, or may have considered, those not participating in the trial as an administrative problem and that it would make matters logistically more difficult—MAJ said 400 members
of the battalion group did not participate in the trial; thereby implying that those who did not participate in the trial were not an administrative or logistic problem. More generally, MAJ agreed soldiers may have misinterpreted the CO’s words to mean that, because the CO was participating, they would have participated in order to deploy. Again, the effect of MAJ evidence was that the fact that 400 deployed soldiers had not participated in the trial belied any expectation that participation in the trial was a prerequisite to deploy. Furthermore, he noted the threat of non-deployment did not make sense when soldiers signed up individually with the AMI trial team, and no record or list was provided to the CO of those who did not participate.

171. BRIG was interviewed on 06 May 2016. Currently, he is the In that capacity he has had but no dealings with him about his complaint. He also served as and is aware of MAJ McCarthy’s situation and concerns about mefloquine. BRIG also acknowledged that he was in the same as MAJ McCarthy and LTCOL.

172. In 2000, then-MAJ was 1 RAR. He recalls there were some concerns the anti-malarial countermeasures used during INTERFET had not been very successful as the rates of malaria in returning battalions was considered too high. The CO 1 RAR, LTCOL Caligari, was concerned about malaria and ensuring that appropriate measures were taken to reduce the incidence of malaria in his battalion. A preventative medication taken once weekly was likely to ensure better compliance than daily taken medication and this was seen as a major advantage in combating malaria. BRIG does not recall when he found out about the trial, but he did participate and suffered no side effects, although he cannot remember which drug he was on.

173. Medical briefings. BRIG recalls receiving two medical briefings, one general and one specific about the trial, and recalls the consent form and it being witnessed by another member. The possible side effects of the drugs were explained to him as per the consent form, and from his perspective the trial was voluntary and you could withdraw at anytime. He was happy to participate in the trial. The briefings on the trial were just one of many in the ‘bull ring’ of force preparation provided to the members of the battalion, who were eager to deploy given the stop start lead up to the deployment. So the trial did not have any particular significance or priority to him. He believed the overall medical supervision and support provided during the trial and upon return to Australia was very good.

174. Then-LTCOL Caligari was described as a leader by example, a great communicator who could speak ‘one-on-one with the diggers, at a boozers parade after a sportos or at a function – he had the common touch to talk from the brigade commander down to the newest IET [soldier]’. He was ‘forceful and considered and [a] very competent battalion commander.’ When speaking with soldiers ‘he hits the chord to motivate, influence or dissuade’ them. LTCOL Caligari gave weekly addresses to the battalion at the Other Ranks’ Canteen and sometimes on parade. During the pre-deployment phase for East Timor, the CO gave regular briefings to the soldiers.
BRIG recalls at one of those pre-deployment briefs to the battalion the CO did discuss the anti-malarial drug trial. He could not remember whether that was before or after the medical briefs. He recalls the CO:

Telling us the trial's on and pitching it as "this is powerful and good for us", ...[t]hat we're going to have extra medical attention and support and be closely monitored ... and I do remember him encouraging the soldiers to participate in it. ... I remember him being very forceful and feeling a little bit uncomfortable about how forceful he had been with the soldiers [in his encouragement] ... about taking part in the trial to ensure that there was enough uptake to make the trial valid.

BRIG explained that by 'forceful' he meant the CO’s address to the soldiers was very theatrical and exuberant, and this style of communication was different to the way he would have spoken. However, it was very effective and the soldiers 'lapped it up'.

The Inquiry put to BRIG the two competing versions of what CO 1 RAR was alleged to have briefed his soldiers about the trial. The first version was that the CO had stated participation in the trial was voluntary but if soldiers did not take part they would not deploy. The second version was the public comment in August 2015 that CO 1 RAR had said the trial was entirely voluntary, he supported it, and that he was going to participate. BRIG responded:

I do not recall, “if you don’t take it you’re not deploying”. I do recall, “I’m taking it.” Or “I’m on it.” And, “we want to reduce non-battle casualties.” And, “I think that this is going to be, you know, important for us and our unit capability.” I remember encouraging words and lead by example. I don’t remember, “If you don’t say yes to this you won’t deploy.” I do not remember this.

BRIG agreed soldiers would absolutely follow LTCOL Caligari’s example. So his comments to the battalion about the trial ‘would’ve influenced them [soldiers] and some of them would’ve felt encouragement. ... And influence ... And some of them could’ve interpreted it as more than that. ... I could understand why some soldiers may have felt more than encouragement than maybe what the CO intended it to be.'

BRIG volunteered that he was a friend of LTGEN Caligari. They had served together in Canberra and their families were friends. He acknowledged receiving an email in late August 2015 from LTGEN Caligari, about the allegations in which LTGEN Caligari provided his version of events. BRIG indicated he was surprised to receive the email, and in hindsight would have preferred that LTGEN Caligari had not sent it. He did not view the email as an attempt to influence what he remembered about the trial; and he denied that he was protecting LTGEN Caligari in anyway. While LTGEN Caligari’s email may have focused his mind on the trial, BRIG description of events was based on what BRIG recalled and not on the brief information contained in the email.

In summary, BRIG believed participation in the 1 RAR anti-malarial trial was voluntary. However, the way the CO expressed his support and participation in the trial was strong encouragement to soldiers, and could no doubt have influenced their decision to participate. He agreed the concept of voluntariness is difficult in a hierarchical environment where soldiers are influenced by command. He provided an example of a recent disciplinary matter where advice
given by a higher ranking member to a soldier was interpreted as compulsion even though there was no intention for it to be taken that way.

180. COL was interviewed on 04 May 2016. He is an ARES member on full time service currently posted to as a project officer. In 2015 he served as the In that capacity he had oversight involvement in managing MAJ McCarthy, and thus is aware of the issues and complaints raised by him concerning mefloquine and the anti-malarial drug trials. COL never met MAJ McCarthy as he was on medical leave for the whole time that he was in 2015.

181. In 2000 then-MAJ was posted as 1 RAR. He participated in the trial, was on mefloquine and does not recall suffering any side effects. COL kept a diary of his deployment to East Timor, which he commenced in July 2000 during the pre-deployment phase. In the diary he noted significant events. He believes he became aware of the trial as early as May 2000. One of the first entries in his diary dated 11 July 2000 is a command group discussion about the difficulties from an operational perspective of managing a blind trial involving two different weekly dose anti-malarial drugs (tafenoquine and mefloquine), and a third daily dose drug (doxycycline) for those members not taking part in the trial.

182. COL remembers receiving the medical briefings by the AMI staff and going through the informed consent process. He ‘made the comment in the diary that I think they sold it quite well. So they explained what this was. They explained what the negatives were ... I remember ... them going through the detailed pluses and negatives of the medication. Basically that these are the risks, these are the benefits.’ It was explained by the doctors that if the drug you were on had a side effect, they would take you off it and you would quickly return to normal. COL stated: ‘the big benefit that was sold to us, was rather than having to do it [take the medication] every day like Doxy you would be able to do this once a week.’ He ‘thought it was a win, a big time win. ... I mean for guys to be able to take a handful of drugs rather than having to take boxes of drugs under a trial was a big win.’

183. The consent form was signed with his Company Sergeant Major (CSM) as his witness in the presence of the doctor (investigator), and the form indicated that the trial was voluntary. Even though it was clear that battalion group personnel did not have to participate in the trial, he stated, ‘I suppose in my case I never thought I wouldn’t do it. ... I could have said no. ... I didn’t feel there would be [any recriminations]. I mean, having said that I probably would have felt like I was probably letting the side down a bit if I didn’t do it because I’m one of the leaders in the battalion, and the CO was doing it, but if I’d felt concern about my own personal health I wouldn’t have done it.’ Nevertheless, there was no compulsion to participate in the trial; ‘there were so many people that weren’t on it, it would be surprising to me that someone would think that it was compulsory.’ COL did not ‘remember there being a groundswell of anti-feeling amongst the soldiers at all, and certainly I didn’t feel obligated to raise any ethical or moral concerns.’

184. COL described the then CO, LTCOL Caligari, as very charismatic and ‘very strong on leadership by example. That was one of his strengths. Communicated very well. So he was very popular I thought with the soldiers because he would speak to them in ways in which they could understand.’ The CO would address the battalion once a week at the Other Ranks’ Canteen.
COL [REDACTED] noted that LTCOL Caligari’s ‘real focus was he didn’t want to bring back any malaria cases and he had learnt from their [2 RAR INTERFET] experience.’ He recalled the drug trial was raised at one of those addresses with the CO explaining ‘there was this trial coming on. He was, I think, more putting it out there as his personal, I’m on the trial, leadership if you know what I mean. So I trust the trial, I’m doing the trial. I think he was saying that more as a dig of confidence. ... He was more putting it out there as a leadership to encourage people to be part of the trial’. COL [REDACTED] had no recollection of the CO in that address using any words about compulsion to participate in the trial stating ‘I’ve heard the claim that the CO made it compulsory. I think that I probably would have recorded that [in his diary].’ COL [REDACTED] had no memory of the CO addressing the battalion on parade about the drug trial.

185. By way of example of matters he recorded in his diary, COL [REDACTED] referred to the CO being very ‘hot’ on soldiers having a Will, based on his experience in Somalia where a soldier died without a Will. The CO told the battalion that everyone had to have a Will to deploy. The entry in COL [REDACTED] diary dated 10 August 2000 says, ‘The CO was very prescriptive about Wills and insurance. He has an interesting bent on this in Somalia’. He stated, ‘I’m pretty sure, given the other things I’ve recorded, if the CO had said something as a discriminator like, “If you’re not in the trial you don’t go”, I’m pretty sure I would have recorded it because I’ve recorded the other things that he has mentioned.’

186. The evidence of the former 1 RAR witnesses concerning the location and words spoken by the CO was put to COL [REDACTED] as was what LTGEN Caligari said in the Defence media release (August 2015). He reiterated that ‘I remember him [LTCOL Caligari] saying - this is at this boozer parade, so my memory is at a boozer parade where he pushed it and he said, “It’s good for Army. It’s good for everyone. It’s a good drug.” He didn’t say it was a good drug, but “It’s good for everyone that we do this trial. I think there’s a lot of value in it. I’m doing it.”’ COL [REDACTED] did not recall any requirement to participate if a soldier wanted to deploy, or any reference to being an administrative problem if you were not participating in the trial.

187. COL [REDACTED] noted there were many officers and soldiers not participating in the trial, and responded: ‘... but to me it would be a dumb thing for him to say when his own RSM, his OPSO, a couple of his other company commanders, all of those guys aren’t on the trial. So to say you don’t go unless you’re on the trial, he’s just discounted his own RSM and his OPSO ... it would seem - well, if he said it would be a pretty rash thing to say, bearing in mind he is basically then saying he’s not taking his RSM and he’s not taking his OPSO.’ Furthermore, any claim that the CO wanted everyone to participate for administrative and logistic ease, ignored the fact there were many officers and soldiers not taking part for various reasons.

188. COL [REDACTED] certainly remembers the CO encouraging soldiers to participate stating, ‘I would refute the fact that he made it compulsory. I would not refute the fact that he strongly encouraged it.’ When asked for a reason why witnesses such as then-MAJ [REDACTED] (whom COL [REDACTED] knows and trusts) would say that the CO had used these words, he responded, ‘The only thing I can think of is that once again he has mistaken the strong endorsement and his [CO’s] own personal recommendation for that [for participating].’

189. COL [REDACTED] advised the Inquiry he had received an email from LTGEN Caligari in August 2015 about the allegations made by MAJ McCarthy, which set out what LTGEN Caligari believed he had said to the battalion. COL [REDACTED] did not see anything untoward about the email.
In his view, LTGEN Caligari was providing information to the key command staff at the time that the 1 RAR anti-malarial drug trial was a media issue and had been referred to in a Senate Inquiry by MAJ McCarthy. COL recollection of events was not influenced by this email, nor did he see it an attempt to influence him. COL does not keep contact with LTGEN Caligari and had not spoken with him since he left the Australian Regular Army in August 2015. He commented that 'I have no reason to protect him and I thought he was a great CO. I thought he did a good job, but if I thought he’d said this I would have no problem supporting the soldiers that are making the claim.'

COL was interviewed on 13 May 2016. He is currently In 2000 he was 1 RAR. COL believed that he did not participate in the trial but was prescribed mefloquine as his anti-malarial instead of doxycycline. His memory of events surrounding the trial was by his own admission very poor. He was not able to provide any definitive information concerning LTCOL Caligari’s address to the battalion and how that impacted on the voluntary nature of the trial. He does recall that the CO was very supportive of the trial, but not any specific detail.

LTCOL provided an email response to Inquiry questions on 25 May 2016. In 2000, he was the 1 RAR. LTCOL became aware of the allegations about the anti-malarial drug trial in 2015 from media reporting. His focus at the time (2000) was not on the drug trial which was one of many pre-deployment briefings (as part of the battle procedure ‘bull ring’), and does not have a good memory concerning it. He believes the trial was voluntary, but it was desirable from an operational perspective that everyone be on a one tablet a week regime. Such a regime would make record keeping easier and ensure better compliance. LTCOL does not recall the parade where LTCOL Caligari addressed the battalion about the trial and thus has no recollection what he may have said about participation. He does believe there was encouragement provided at command groups and similar meetings (rather than at a parade) to participate in the trial because of the perceived benefits.

COL now a Reserve Officer, was the 1 RAR in 2000. In an email dated 23 May 2016 sent from overseas, he indicated that he was not a participant in the trial and was not involved in its administration as that was a matter for the Accordingly, COL had little memory of the trial and his mind was focused on other operational matters. He recalls there was a parade where the CO discussed the drug trial, but he cannot remember the specifics of what was said.

MAJ has been retired from the Army for many years and his email contact details were provided by LTGEN Caligari towards the end of the evidence gathering phase of the Inquiry. MAJ subsequently provided answers by email to a number of questions.
194. In 2000 MAJ was the 1 RAR and in that role was responsible for all the administrative and logistics preparation for the deployment of the battalion group. As the medical area was one of several administrative areas that he organised and oversaw during the preparation for deployment. In that role he was responsible for the oversight of the 1 RAR anti-malarial drug trial. He participated in the trial and although informed upon his return to Australia what drug he took, he now cannot remember what that was. From his perspective the trial was voluntary and from memory capped at 600 participants.

195. The Inquiry was informed by MAJ that the administrative requirements for members to volunteer to participate in the trial were part of the administrative program preparing members for deployment. This required participants to fill in paperwork including signing a consent form volunteering for the trial (the same one which had been forwarded to him by the Inquiry). He also believed that blood samples were taken for testing. He gave evidence that LTCOL (the principal trial investigator from AMI) was ‘adamant that everything had to conform to the correct trial protocols to ensure the validity of the information gained and the accuracy of the results.’ MAJ had no direct role in the actual administration of the trial paperwork.

196. An example was provided by MAJ of how concerned LTCOL was about conforming to the trial protocols, ‘I clearly remember on the day when I was being interviewed to sign the form that the soldiers with me had to be directed to read the information as they just wanted to sign it and move on to the next part.’

197. MAJ remembers the CO LTCOL Caligari addressing the battalion about the background, nature and importance of the trial and he thinks that this occurred on the parade ground, but is not sure. He can not recall the exact words spoken, but the CO ‘did clearly say that the trial was voluntary and that members would have to volunteer in writing, he did say that he was a volunteer for the trial, and I cannot remember the details but he made a logical case for the value of the trial not only to 1 RAR during our deployment but also to Defence into the future.’ MAJ said that the COs comments were ‘in keeping with one of his prime objectives for the deployment which was to ensure that not one member of the Bn Gp got Malaria’.

198. MAJ indicated the CO ‘definitely told the Battalion that the trial was voluntary. I cannot remember him saying that, “If you did not volunteer then you would not deploy”. As the person responsible for manning the Battalion OR for the deployment I can categorically state that this was not one of the personnel selection criteria.’ He believed that the CO encouraged participation in the trial, but that this could not be interpreted as a direction to do so; and stated, ‘IF IT HAD BEEN A DIRECTION then I would have been the one responsible to implement it and I was never given such a directive’.

199. A reason was put forward by MAJ as to why soldiers may have interpreted the CO’s address as a direction. He believed, given the stop start background to 1 RAR’s deployment in the previous year, soldiers were extremely keen to deploy and did not want to give anyone an excuse to leave them behind, such as not participating in the trial, particularly when the CO was participating. He believed the soldiers certainly could have viewed the CO’s comments as an expectation that they would participate in the trial.
200. MAJ did recall LTCOL raising with the CO that there may have been an initial slow uptake for the trial, and the ‘CO decided that he needed to impress the Bn that this was actually a very important issue. This was not an uncommon happening with soldiers and Admin issues.’

LTGEN John Caligari (Retd)

201. In MAJ McCarthy’s submission to the Senate Inquiry in July 2015, LTGEN Caligari was referred to as ‘the Commanding Officer (who is now a Lieutenant General)[who] directed that any of his subordinates who did not ‘volunteer’ to participate in the trial would be excluded from the deployment.’ Defence responded to media inquiries about the issue on 28 August 2015, stating that: 

Lieutenant General Caligari did not tell anyone under his command that they would not deploy to East Timor if they refused to participate in the Army Malaria Institute (AMI) trial. He briefed his Battalion that the trial was entirely voluntary, that he supported the trial and that he was going to participate in the trial.’

202. LTGEN Caligari joined the Army in 1979 and retired in August 2015 as Chief of Capability Development Group. During his service he held command appointments at the unit, brigade and division/contingent level. He had several operational deployments, including to Somalia in 1993 as a company commander with 1 RAR. In 2000, then-LTCOL Caligari was posted as CO 1 RAR and deployed the battalion to East Timor later that year for six months.

203. Prior to their deployment in October 2000, 1 RAR had gone through a stop start routine having expected to deploy with INTERFET in September 1999. So when the unit was told it would deploy, the soldiers were ready and eager to deploy. LTCOL Caligari was aware of the malaria problem that had been experienced by 2 RAR and 3 RAR in 1999/2000 as a part of INTERFET, and wanted to ensure his troops did not contract malaria.

204. LTGEN Caligari recalls he first became aware of the anti-malarial drug trial when LTCOL from AMI approached him. LTCOL told him about his directive to conduct a trial in 1 RAR; however, the trial ‘was entirely voluntary and if none of the soldiers signed up, then none of the soldiers signed up.’ LTCOL talked about the need for the change in a malaria prophylaxis, because there were some resistant strains of malaria, particularly in East Timor, and there was going to be a trial of an alternative anti-malarial drug. The trial had been endorsed by ADHREC and it was all considered safe. LTGEN Caligari recalled that mefloquine was actually a drug that had been used for decades by the US military in particular. LTCOL explained that the principal trial drug was tafenoquine, it was going to be double blind trial, and that LTCOL wanted the CO’s permission to speak with battalion members. LTGEN Caligari indicated he told LTCOL to ‘fill his boots’, meaning that he had approval to speak to the battalion. At that time, which was around July/August 2000, an announcement to the battalion notifying the conduct of the trial would have been passed down through unit orders.

205. The advantage of the new drug that attracted LTCOL Caligari was that it was taken once a week. He knew from his deployment experience in Somalia that compliance with soldiers taking a doxycycline tablet daily was problematic. As far as LTCOL Caligari was concerned the trial was a direction from Army and although his initial view was to support the trial, it would be left up to the soldiers to decide whether to participate or not. He recalls that sometime after their initial meeting and LTCOL briefing some 1 RAR soldiers, he (LTCOL approached him again
and indicated that he needed assistance to ensure there was a sufficient uptake of the trial by soldiers. LTCOL [redacted] gave the CO a more detailed brief to further convince him of the merits of the trial, and advised that AMI would provide full medical support throughout the trial, including in East Timor. LTCOL Caligari was convinced about the merits of the trial and told LTCOL [redacted] he would address the battalion and tell them the trial was worthwhile and that he was participating.

206. Although LTCOL Caligari had weekly addresses to the battalion at the Other Ranks Canteen on sports afternoon, on this occasion he spoke to the battalion on parade and not in the canteen. He could not remember exactly when it occurred, but it was after the initial briefings given by LTCOL [redacted] to the battalion. LTGEN Caligari indicated that his address:

went something along the lines of “We’ve got a trial coming up. This trial is important to Army. It needs another drug. There were a number of malaria cases in 2 RAR. Not getting malaria is very important.” I ran through a bit of history of the impact of malaria on wars over the years. I said, “It is very important to me that we don’t get any malaria in the battalion”. I said to the battalion, “I’ve had the briefing. I’m convinced this is worthwhile. I will be joining the trial.”

207. LTGEN Caligari went on to explain that a CO had to very careful about the use of his position and authority. By this he meant that if a CO endorsed a product or said something was worthwhile, then soldiers would inevitably think it was. Accordingly, he reinforced to the battalion that the trial was voluntary. He went on to say:

My reinforcement of it was, “I’m joining the trial. I see the importance of this. This is important to me not to get malaria”. I said to them, “I don’t want malaria. I’m signing up. It would be good if we could get the minimum number required”, and I can’t remember off the top of my head what that was. “However, you all need to understand this is completely voluntary. You will be required to sign a piece of paper where you will be volunteering, ...” So I said to the soldiers, “You are volunteering or not. I’m just telling you from my perspective it’s important and I’m volunteering”. That’s a powerful message.

By his choice of words, LTGEN Caligari in effect acknowledged that by telling the soldiers, ‘I think this is worth getting on board to help Army out [by] volunteering, but you have to volunteer’, it was a powerful message to volunteer and participate in the trial.

208. However, he refuted the allegation made by MAJ McCarthy that it was a direction, stating:

I am denying I directed soldiers to take any drug or that I even threatened them that they wouldn’t deploy. ... I deny that emphatically. In fact, for me, the evidence that we deployed with over 1300 soldiers over the six-month period and only 600 I think it was 654 signed up. That means there’s nearly half the battalion didn’t. ... So if someone thought they were compelled to sign up in order to deploy, there’s pretty good evidence to suggest that lots and lots got to deploy without signing up.
209. The evidence of the six former 1 RAR witnesses, identified by MAJ McCarthy, about what they believed the CO had said, was put to LTGEN Caligari. He denied using any of the words alleged and the reasons he might have said those words suggested by them, other than his saying the trial was voluntary. Initially, he could not think of a reason why these members would say deployment was dependent on participation in the trial. LTGEN Caligari then commented that very few things in the Army are voluntary. So his words may have been interpreted by those soldiers to mean the trial was not voluntary. He went on to say he recalled early in 2000 when taking over from the previous CO, he had told the battalion on parade that if members wanted to go to East Timor (in the future), they needed to pass their Battle Fitness Assessment. This was his only recollection of using directive words.

210. When COL 10 August 2000 diary note about the need for a Will was raised with LTGEN Caligari, he agreed he had been prescriptive about having a Will, but that was speaking to the command group and not to the battalion parade.

211. In summary, LTGEN Caligari agreed his words would have encouraged soldiers to participate and in some cases there may have been an expectation that if the CO was participating, then everyone should. He said:

\[
\text{The authority of a CO is paramount. When the CO says something, it's not a matter of, "Is that a good idea or not? Should we do that or not?" and particularly when the CO is addressing the entire battalion. You need to be very careful with that authority. So I have no doubt that 16 years after the event, someone may have thought, particularly if they're suffering now, may very well have thought I'm pretty sure I was told to take that. I could completely understand that. ... The majority of diggers would have gone, "Well, if the CO's doing it, what the hell". And by the way, it's one a week, which was the other big selling point.}
\]

212. However, LTGEN Caligari was adamant the trial was voluntary and he told the soldiers that it was ‘It had been voluntary since the day turned up.’ He agreed soldiers were a captive audience in the military hierarchical system. A decision whether or not to participate in the trial was one of many deployment matters a soldier had to tick the box in order to deploy. He went on to say:

\[
\text{the Army is about compulsion, so any of these diggers would have said, "Okay, well we're going to Timor. We're doing a drug trial. The CO's reinforced he's happy with it, let's go on with it". ... No one would have said, "I get a choice all the time. I'm going to make a serious decision here". It would have been, "There's a drug trial on. So what. The CO's doing it. He's agreed."}
\]

213. LTGEN Caligari was questioned about the email dated 30 August 2015 he sent to former company commanders, the 2IC, OPSO and ADJT, which outlined his version of events of his address to the battalion. In the email LTCOL Caligari said in response to MAJ McCarthy’s allegation:

\[
\text{This is most definitely not what I said. ... My recollection is that the AMI team briefed everyone and expected everyone would sign up. Very few did, and the AMI team asked for help! I made it clear to the soldiers on parade one day that I thought the outcome of}
\]
confirming a better regime for malaria management for Army was worth it and that I would be signing up for the trial. I can remember explaining the importance of having sufficient people involved in the double blind trial, but reinforced that it was a voluntary sign on. If I remember rightly, anyone who was due to leave the Bn in Jan 01 and all of their reinforcements were excluded from the trial.

He indicated the purpose of his email was not to influence the memory of others involved, but to alert them to the issue:

My primary concern was that if they had soldiers, and all of these company commanders have good networks with their own soldiers, if they had soldiers questioning them who were thinking, “Well I trust you. What do you think happened”, if they felt like they didn’t know or they couldn’t remember, they would then turn to someone to remind them. I was giving them what I considered to be my version of events and this is how a simple explanation can be explained to soldiers who may ask you.

214. The general conduct of the trial was discussed with LTGEN Caligari. He indicated he was prescribed mefloquine and suffered no side effects during or after the trial. LTGEN Caligari was satisfied the potential side effects of both drugs were explained to him, and he had no concerns with the conduct of the trial. Medical support was provided by AMI in Australia and in East Timor.

LTCOL was asked to comment on LTGEN Caligari’s evidence about the initial reluctance of 1 RAR soldiers to take up the trial resulting in LTGEN Caligari addressing the battalion. LTCOL had not raised this issue in his earlier evidence to the Inquiry, nor that he had requested assistance from CO 1 RAR. He responded by email on 24 May 2016 stating:

I most certainly did speak to Gen Caligari more than once over the course of the study and it may well have been that I reinforced the importance of maximising recruitment - I would be surprised if I didn’t. While I do not recall a specific meeting discussing recruitment it is highly likely that this would have been subject to a conversation. I do not recall specifically raising concerns on recruitment but any conversation related to the importance of recruiting numbers could be interpreted as such - especially in the first few recruiting days when processes would have been less refined and we were still working with the 2IC to get access to the soldiers - I do know that we struggled to support the first group or so as I had to bring additional resources up from Brisbane to meet the clinical load in pre-deployment workups. The CO had an active interest in the study from these early days and we would have discussed progress at each of the times we crossed paths - and it would be entirely plausible that he would have interpreted my comments [the] many times we meet during this period as indicating a concern re recruitment. On balance I can agree that I would have encouraged the CO/2IC to provide focussed encouragement for, and access to, his personnel to consider participation. The exact setting for establishing this I do not recall but have no reason to doubt the recall of the CO/2IC.’
Analysis and assessment of evidence (Tafenoquine trial)

216. A common theme from the evidence of nearly all 14 witnesses is that their memory of most aspects of the 1 RAR anti-malarial trial conducted 16 years ago is either vague or non-existent. The trial briefings were one of many pre-deployment matters required to be completed prior to departing on a much anticipated and sought after deployment to East Timor by 1 RAR. At the time, the anti-malarial drug trial was not considered a significant and high priority matter to most participants.

Informed consent: drug side effects

217. The first aspect of informed consent is that trial participants must be informed, at their level of comprehension, of relevant aspects of the trial, in particular the potential side effects of the drugs being administered. The evidence from the Principal Investigator of the consent process is not directly challenged by any witness and is accepted by the Inquiry. Given the experimental nature of one of the drugs (tafenoquine), a three stage briefing process was conducted, culminating in a witnessed consent form being signed before a medical officer (AMI trial investigator). This process was followed to ensure participants were aware of the potential side effects of both drugs and that the trial was a voluntary trial, without detriment to deployment, and they could withdraw at any time.

218. Most witnesses have little or no memory of the informed consent process. However, nearly all accept the medical briefings dealt with the potential side effects of the drugs and that the trial was voluntary. Most witnesses recall they were told, or they believed, both drugs were safe, as reflected in the consent form. Two witnesses, BRIG [REDACTED] and COL [REDACTED] both in 2000, have a good memory of the consent process and confirm the evidence provided by LTCOL [REDACTED] (principal medical investigator) of the process, including the explanation of potential side effects and the voluntary nature of the trial.

219. The focus of the AMI investigators and the ethics committee (ADREC) was on the experimental drug tafenoquine to ensure participants were fully aware of its potential side effects as they were known at the time. The evidence provided to the Inquiry does not support a claim that tafenoquine causes permanent neurotoxic or other permanent side effects. The Inquiry is satisfied the known potential side effects of tafenoquine were properly disclosed to trial participants.

220. As a registered drug in Australia, mefloquine (brand name Lariam) has approved written Product Information and CMI, the latter usually provided as a leaflet to patients who are prescribed the medication. The evidence is that the trial consent form did not include every possible mild side effect of mefloquine listed in the 1998 Lariam CMI. It did however disclose two of the three serious, but rare, side effects listed in the CMI, namely anxiety and depression. Seizure is listed in the 1998 CMI however it was not included in the trial consent form.

221. A cause of potential concern is the reference in the trial consent form to a rare, one in 10,000, possibility of anxiety or depression occurring in trial participants taking mefloquine. BRIG [REDACTED] evidence was the risk of anxiety or depression occurring in trial participants was actually closer to around one in 1000 and described in the 1998 Product Information as 'uncommon', rather than 'rare'. The Inquiry assesses it would have been preferable in the trial consent form to use the same qualitative language about anxiety and depression as was used in the
CMI rather than to use quantitative measures. The difficulty is the ambiguity in the terms, such as 'uncommon' and 'rare', used in the Product Information and similar terms, such as 'rarely', used in the CMI. In apparent contradiction to the 1998 Lariam Product Information, the 1998 Lariam CMI (ordinarily given to patients) states that anxiety and depression are serious side effects, but considered 'rare'.

222. Accordingly, the Inquiry finds the description used in the trial consent form that the likelihood of anxiety or depression was considered 'rare' was consistent with the 1998 Lariam CMI, which was ordinarily given to individuals prescribed Lariam (mefloquine), and was not misleading. The decisions not to include in the consent form every mild side effect of mefloquine contained in the 1998 Lariam CMI and particularly not to include 'seizure' as a rare serious side effect, did not of themselves invalidate the informed consent process. This was because the determinative factor relied on by many witnesses appears to have been that the consent form said both drugs were considered safe to use. As mefloquine was an approved and registered TGA drug, inclusion of the information that it was safe to use in the consent form was reasonable.

223. The Inquiry finds the consent form and the medical briefings provided to trial participants were not inconsistent with the information contained in the 1998 CMI. In the context of a trial of an experimental drug (tafenoquine), using a registered drug (Lariam - mefloquine) as a control, the Inquiry is satisfied the consent form contained sufficient relevant information of the potential side effects of mefloquine in a form comprehensible to trial participants, in order to allow them to make an informed decision whether or not to participate in the trial.

224. In the 1 RAR trial, mefloquine was used by approximately one-quarter of the participants as a control or comparator drug to the experimental tafenoquine. There were no reported serious adverse neurological or psychiatric side effects from the use of mefloquine (or tafenoquine). The six witnesses identified by MAJ McCarthy all took tafenoquine. MAJ McCarthy's complaint to the IGADF and the Senate Inquiry focuses on the alleged neurotoxic effects of mefloquine (not tafenoquine), in particular the failure of AMI to ensure that trial participants were 'informed of the foreseeable likelihood of permanent brain injury with long term or permanent side effects' of mefloquine. The evidence reveals that mefloquine neurotoxicity (permanent brain or Central Nervous System (CNS) injury) was (and is) not accepted by Defence health authorities (now JHC) or the AMI investigators as a potential side effect of mefloquine, and in their view MAJ McCarthy's claim is not supported by valid scientific research.

225. The Inquiry was not directed to inquire into the side effects of mefloquine use. However, the AMI investigators did not act unethically or unreasonably by not disclosing mefloquine neurotoxicity as a potential side effect in medical briefings or in the trial consent form. The Inquiry has come to this conclusion because the consent form was consistent with the 1998 Product Information and CMI, which do not recognise and include mefloquine neurotoxicity as a possible side effect of mefloquine use. Accordingly, the informed consent process was not invalidated by the omission of mefloquine neurotoxicity as a potential (or, as MAJ McCarthy has asserted, a foreseeably likely) side effect of taking mefloquine.

226. In summary, the Inquiry is satisfied the trial participants were appropriately informed by the medical investigators of the potential side effects of both tafenoquine and mefloquine, and understood that participation in the trial was voluntary without detriment to deployment or future career.
Informed consent: voluntary participation

227. The second complaint concerning the 1 RAR trial was the allegation participation in the trial was not voluntary because the CO, then-LTCOL Caligari, informed the battalion that those who did not participate in the trial would be excluded from the deployment. LTGEN Caligari has denied the allegation since it was first made by MAJ McCarthy to the Senate Inquiry in July 2015.

228. Those witnesses identified by MAJ McCarthy generally had a poor memory of the circumstances surrounding the 1 RAR trial, which is not unexpected considering it occurred 16 years ago and was one of many events during a busy pre-deployment phase. The Inquiry accepts that none of the witnesses, all of whom were on tafenoquine and not mefloquine, has an ‘axe to grind’ with Defence or the former CO by coming forward many years later about the voluntary nature of the trial. Three witnesses said they suffered no side effects attributable to tafenoquine, while the other three would like to know whether ongoing medical issues they are suffering from could possibly be linked to their use of tafenoquine. They all respected LTCOL Caligari as a CO and would have participated in the trial in order to deploy, even if they had not believed the CO had made participation in the trial a prerequisite for deployment. In their view the drug trial was not a significant event and they believed the Army would not give them a drug that was not safe, which is consistent with the medical briefings and consent form.

229. All of the six witnesses identified by MAJ McCarthy recall the CO addressing the battalion either on parade or in the Other Ranks Canteen about the trial and stating words to the effect that if they did not participate in the trial they would not deploy. There were slight variations of what was actually said with one witness saying the CO said he would ‘reconsider’ deployment for non-participants, and another saying the CO stated that to deploy non-participants would be an ‘administrative problem’. One witness also speculated the CO made the participation a prerequisite for deployment because it would be an administrative burden to have some on the trial and others not. All witnesses believe they did not misinterpret encouragement or an expectation by the CO of participation as a direction or threat that non-participation would result in non-deployment. While no witness could remember the specific words used, the message to them was clear that it was a requirement to participate in the trial in order to deploy.

230. The Inquiry accepts that all of the six witnesses 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. However, the Inquiry assesses that the witnesses’ overall memory of events surrounding the anti-malarial drug trial, conducted during a busy pre-deployment 16 years ago, is generally poor and lacking detail.

231. All six witnesses either remember or accept that the CO addressed the battalion in some detail about the anti-malarial drug trial and informed them that he supported the trial and was participating. Four witnesses specifically say he said the trial was voluntary but then added ‘words to the effect’ that the deployment was conditional on participation. All relevant witnesses accepted that the CO was very focused on taking all necessary precautions to prevent 1 RAR soldiers contracting malaria in light of previous INTERFET experience. This Inquiry accepts that, as a consequence, when the CO addressed the battalion he actively sought to encourage participation in the voluntary drug trial, which he fully supported and was participating in, and which he believed would assist in the prevention of malaria. What is in issue is whether the CO also indicated the deployment was in effect conditional on participation in the voluntary trial.
232. Evidence was received from eight witnesses who held key command appointments within the battalion at the time. From their perspective the trial was voluntary. No witnesses recalled the CO saying to the battalion words to the effect that if soldiers did not participate in the trial they would not deploy. COL _____ and MAJ _____ do not recall the CO addressing the battalion, but both are adamant it would be out of character and inconsistent with his leadership style to have said the trial was voluntary, and then say if you do not participate you do not deploy. The Inquiry accepts that if they had heard such words they (and other company commanders) would have challenged the CO about it, such was the relationship between the CO and his command team.

233. The suggestion that the CO referred to, or may have considered, those not participating in the trials as an administrative or logistic problem, is not supported by the evidence. The Inquiry accepts the evidence of the former LTGEN Caligari and the CO himself (LTGEN Caligari) that such a view or comment did not make sense as there were over 400 members of the battalion group who did not participate in the trial and were taking doxycycline. The fact that over 400 soldiers did not participate in the trial also provides some support to LTGEN Caligari’s and MAJ _____ comments that such large numbers of non-participants is not consistent with the CO directing or threatening that soldiers who did not participate in the trial would not be deploying to East Timor.

234. COL _____ did not recall the CO addressing the battalion on parade about the drug trial, but does remember him doing so at the Other Ranks Canteen. While the CO told the soldiers that he trusted the trial, it was good for the Army, good for everyone, he was participating and strongly encouraged their participation, he did not use any words of compulsion by threatening non-deployment if they did not participate. COL _____ kept a contemporaneous diary of the deployment detailing key events. Where the CO made memorable or important comments, such as his prescriptive remarks about the need for a Will, COL _____ made a record in his diary. The Inquiry accepts, as credible, COL _____ evidence that had the CO made the alleged comments (participation being a requirement for deployment in a voluntary trial), it would have been a very unusual comment, and COL _____ would most likely have made a diary note (unless he was not present at the parade).

235. BRIG the former 1 RAR, has a reasonably good memory of events concerning the anti-malarial trial during the pre-deployment phase of the operation. He is one of two officers who specifically recall the CO addressing the battalion on parade about the drug trial. The Inquiry assesses his detailed evidence, which is not selective of some events over others, as likely to be reliable on the range of issues surrounding the drug trials, including the medical briefs. BRIG _____ recalls the general content of the CO’s address to the battalion, which goes beyond the brief information revealed to him in LTGEN Caligari’s email of 30 August 2015. His evidence is consistent with the later evidence provided to the Inquiry by LTGEN Cagliari. BRIG _____ has a strong recollection of the CO’s endorsement of the trial and the CO leading by example, but no recollection of the CO saying words to the effect, that although the trial was voluntary, if you do not participate you will not deploy. His opinion that some soldiers would have been influenced or encouraged by the CO’s words, and that others may have felt more than encouragement to participate in the trial, is assessed as a reasonable and likely reflection of actual events.
236. MAJ the 1 RAR in 2000, was the responsible officer in 1 RAR for the administration of the anti-malarial drug trial. He also recalls the CO addressing the battalion on the background, nature and importance of the trial. This followed a conversation with LTCOL about the initial slow uptake by soldiers. He corroborates the evidence given by LTGEN Caligari and BRIG and although he cannot remember the exact words spoken he definitely remembers the CO saying the trial was voluntary and logically arguing the case for the value of the trial to the unit and to Defence into the future. He does not remember the CO saying words to the effect that if you do not volunteer for the trial then you would not deploy. Had this been a direction by the CO, as he would have been responsible for ensuring its implementation and this did not occur. MAJ indicates the CO clearly encouraged participation in the trial but his words could not be interpreted as a direction. The Inquiry assesses his evidence as clear and definitive, and likely to be credible.

237. The Inquiry assesses the evidence of the command group witnesses was not influenced by the email from LTGEN Caligari sent on 30 August 2105, when the issue was first raised in the media and prior to any Inquiry being undertaken into the matter. LTGEN Caligari provides a reasonable explanation to why he sent the email and the Inquiry is satisfied the purpose of the email was not intended by him to influence the memory of others involved.

238. The Inquiry is satisfied the CO addressed the battalion about the trial and encouraged them to participate following a conversation with LTCOL resulting in him (the CO) believing that without his support for the trial there may not be sufficient participation.

239. LTGEN Caligari’s evidence to the Inquiry was confident and convincing. He made a strong argument that his authority as CO meant any suggestion or endorsement by him of a course of action or a product would inevitably lead to it being taken up by most soldiers. The Inquiry is satisfied that the CO did not need to threaten soldiers with non-deployment if they did not participate in the trial, as by strongly supporting it and telling them that he was volunteering, he would achieve his aim of ensuring sufficient participation in the trial by 1 RAR soldiers.

240. The Inquiry also finds it highly unusual for a CO, particularly one with then-LTCOL Caligari’s leadership and communication skills, which were acknowledged by all relevant witnesses, on the one hand to say the trial was voluntary and, on the other, then to threaten non-deployment for those who did not participate. Such a blatant and contradictory comment was not only unnecessary to achieve his aim, but would likely have resulted in the matter being raised with him by the command team, and perhaps the matter being brought to the knowledge of others in authority at the time. The fact this did not occur is supportive of LTGEN Caligari’s adamant denial that he did not make the alleged comments threatening soldiers with non-deployment.

241. There is evidence from LTCOL that during the medical briefings and consent process a small number of soldiers expressed a belief that they had to participate in the trial, commenting this information perhaps came from their immediate supervisors in the unit, but not the CO. While this misapprehension was quickly corrected by LTCOL one possible explanation for such a belief was provided by LTGEN Caligari. He suggested that the Army is all about compulsion and things are seldom voluntary, and therefore soldiers may have an expectation that they must participate, even when they have a choice. In any event LTCOL also provided anecdotal evidence that during the signing of the consent forms, there were a number of soldiers who chose not to participate in the trial, who were not excluded for other reasons,
indicating that some soldiers did exercise their choice and still deployed. (In order to protect their identities separate trial data was not kept of the numbers.)

242. The Inquiry assesses there was strong encouragement to participate in the trial from the CO, and the benefits of the trial were promoted by the AMI medical investigators (who also said the drugs were safe). This likely led to an expectation by command and soldiers themselves that everyone would participate in the trial. The six witnesses identified by MAJ McCarthy all denied that they had misinterpreted the intent of the CO’s strong encouragement. Based on the evidence of relevant witnesses, a decision to participate or not in the trial was not a significant issue to them; rather their participation decision was just another tick in the pre-deployment list of things to be completed so they could deploy. No witness can remember the actual words the CO is alleged to have said, but rather the ‘effect’ of what he said. Given the intensity of a pre-deployment environment, it is possible some of those present for the CO’s address, including the six witnesses identified by MAJ McCarthy, 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; or alternatively, as an expectation that they were required to participate as part of the deployment.

243. In summary, the Inquiry finds that there is differing but credible evidence provided by the six witnesses identified by MAJ McCarthy, and the command group officers and LTGEN Caligari. Furthermore, the explanation given by LTGEN Caligari as to why he did not threaten or direct non-deployment for soldiers not participating in the trial is reasonable in the circumstances. Accordingly, the Inquiry is not satisfied to the required standard of proof of the sufficiency or quality of the evidence to make an adverse finding that the CO said the alleged words (or made a similar threat or direction) to the effect that participation in the trial was required in order to deploy to East Timor.

244. Both BRIG and LTGEN Caligari raise the issue of voluntariness and compulsion in a hierarchical environment where soldiers are influenced by command. The Inquiry is satisfied the voluntary nature of the anti-malarial drug trials was clearly reinforced during the medical briefings and consent process, and that consent was both informed and voluntary in compliance with the NHMRC guidelines. However, the ready acceptance by soldiers of advice or encouragement provided to them by military persons in authority, combined with a potential belief that participation in the trial was expected, is an issue worthy of further consideration in the conduct of any future medical trials, particularly in the context of pre-deployment for an overseas operation.

Informed consent: drug side effects findings

**FINDING 13:** In compliance with NHMRC guidelines, participants in the 2000 to 2002 anti-malarial drug trials conducted by AMI were required to voluntarily confirm their willingness to participate in the trial, that is, exercise a voluntary choice, after having been informed at their level of comprehension of relevant aspects of the trial including the risks and discomforts (side effects) associated with taking the drugs. There were not to be any adverse consequences for failing to participate in the trial, including a threat of non-deployment to East Timor.
FINDING 14: Participants in the 1 RAR tafenoquine/mefloquine anti-malarial drug trial undertook a comprehensive three phase medical briefing process culminating in a witnessed consent form being signed before a medical officer. This process ensured that participants were aware of the potential side effects of both drugs and that the trial was a voluntary trial, without detriment to deployment, and they could withdraw at any time.

FINDING 15: Most of the 14 witnesses interviewed in the 1 RAR trial had a limited and vague memory of the informed consent process. Nearly all accept that the medical briefings dealt with the potential side effects of both drugs and that the trial was voluntary. Most witnesses recall that they were told, or believed, that both drugs were safe. Two witnesses, with a good memory of the consent process, confirm the evidence provided by the principal medical investigator of the trial process, including the explanation of potential side effects and the voluntary nature of the trial.

FINDING 16: The focus of the AMI investigators in the 1 RAR trial was on the experimental drug tafenoquine. The known potential side effects of tafenoquine were properly disclosed to trial participants. No credible evidence was provided that in 2000 tafenoquine was known to potentially cause permanent neurotoxic or other permanent side effects.

FINDING 17: Mefloquine (brand name Lariam) is a registered drug in Australia and has approved written product information and consumer medicine information (CMI). The trial consent form did not include every possible mild side effect of mefloquine listed in the 1998 Lariam CMI, but did disclose two of the three serious, but rare, side effects listed in the CMI, namely anxiety and depression (but not seizure).

FINDING 18: The trial consent form statement that the likelihood of anxiety or depression was considered rare was consistent with the 1998 Lariam CMI, which was ordinarily given to individuals prescribed mefloquine. The failure to list seizures as a rare serious side effect and every one of the many mild side effects of mefloquine contained in the CMI, did not of itself invalidate the informed consent process.

FINDING 19: The consent form and the medical briefings provided to trial participants were not inconsistent with the information contained in the 1998 CMI. In the context of a trial of an experimental drug (tafenoquine), using a registered drug (Lariam - mefloquine) as a control, the consent form contained sufficient relevant information of the potential side effects of mefloquine in a form comprehensible to trial participants, so as to allow them to make an informed decision whether or not to participate in the trial.

FINDING 20: The AMI investigators did not act unethically or unreasonably by not disclosing to trial participants ‘mefloquine neurotoxicity’ (permanent brain or Central Nervous System injury) as a foreseeable likely side effect of taking mefloquine. The trial consent form was consistent with the 1998 Lariam product and consumer medicine information forms, which did not recognise and include mefloquine neurotoxicity as a possible side effect of mefloquine use. Defence health authorities and the AMI investigators also did not recognise or accept ‘mefloquine neurotoxicity’ as a possible side effect of taking mefloquine.
FINDING 21: 1 RAR trial participants were appropriately informed by the medical investigators, in a manner comprehensible to them, of the potential side effects of both tafenoquine and mefloquine, and understood that participation in the trial was voluntary without detriment to deployment or future career and they could withdraw any time during the trial.

Voluntary participation findings

FINDING 22: CO 1 RAR was focused on taking all necessary precautions to prevent 1 RAR soldiers contracting malaria. Consequently, he addressed the battalion in detail about the malaria issue, and in doing so actively sought to encourage participation in the voluntary drug trial, which he fully supported, was participating in, and believed would assist in the prevention of malaria in the unit.

FINDING 23: The evidence of the six witnesses identified by MAJ McCarthy, with slight variations, was that CO 1 RAR (then-LTCOL John Caligari) said words to the effect if soldiers did not participate in the voluntary trial, they would not deploy. While none of the six witnesses could remember the specific words used, the message to them was clear that it was a requirement to participate in the trial in order to deploy. All six witnesses believe they did not misinterpret encouragement or an expectation by the CO of participation as a direction or threat that non-participation would result in non-deployment.

FINDING 24: All of the six witnesses identified by MAJ McCarthy 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. However, the witnesses’ overall memories of events 16 years ago surrounding the anti-malarial drug trial, which was conducted during a busy pre-deployment phase, are generally poor and lack detail.

FINDING 25: The suggestion by two witnesses that CO 1 RAR referred to, or may have considered, those not participating in the trials as an administrative or logistic problem, is not supported by the evidence, as there were 400 members of the battalion group who did not participate in the trial.

FINDING 26: Evidence received from eight witnesses who held key command appointments within the battalion was that the trial was voluntary, and none of those eight 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.

FINDING 27: The former 1 RAR provided credible evidence of a strong recollection of the CO’s endorsement of the trial, but no recollection of the CO saying words to the effect, that although the trial was voluntary, if you do not participate you will not deploy. His opinion that some soldiers would have been influenced or encouraged by the CO’s words and others may have felt more than encouragement to participate in the trial, is a reasonable and likely reflection of actual events.

FINDING 28: The former 1 RAR provided credible evidence he definitely remembered the CO saying the trial was voluntary and logically arguing the case for the value of the trial to the unit and to Defence into the future. He did not remember the CO saying words to the effect that
if you do not volunteer for the trial then you would not deploy. The CO clearly encouraged participation in the trial, but his words could not be interpreted as a direction.

FINDING 29: CO 1 RAR addressed the battalion about the trial and encouraged them to participate following a conversation with the principal medical investigator resulting in him (the CO) believing that without his support for the trial there may not be sufficient participation.

FINDING 30: CO 1 RAR did not need to threaten soldiers with non-deployment if they did not participate in the trial, as by strongly supporting it and telling them that he was volunteering, he would achieve his aim of ensuring sufficient participation in the trial by 1 RAR soldiers.

FINDING 31: The alleged blatant and contradictory words by CO 1 RAR to the effect that although the trial was voluntary, if soldiers did not participate they would not deploy, would likely have resulted in the matter being raised with him by the command team, and perhaps being brought to the knowledge of those in authority at the time. The fact this did not occur is supportive of LTGEN Caligari’s adamant denial that he did not make the alleged comments threatening soldiers with non-deployment.

FINDING 32: There was strong encouragement to participate in the trial from CO 1 RAR, and the benefits of the trial were promoted by the AMI medical investigators. This likely led to an expectation by command and soldiers themselves that everyone would participate in the trial. It did not occur to most soldiers not to participate. A decision whether or not to participate in the trial was not a significant issue to them; rather, that decision was just another tick in the pre-deployment list of things to be completed.

FINDING 33: No witness could remember the actual words CO 1 RAR is alleged to have said, but rather the ‘effect’ of what he said. Given the intensity of a pre-deployment environment, it is possible some of those present for the CO’s address, including the six witnesses identified by MAJ McCarthy, 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; or alternatively, as an expectation that they were required to participate as part of the deployment.

FINDING 34: Defence members were not compelled to take mefloquine or tafenoquine during the 1 RAR anti-malarial drug trial. There is differing but credible evidence provided by the six witnesses identified by MAJ McCarthy, and the former command group officers and LTGEN Caligari concerning voluntary participation in the trial. The sufficiency and quality of the evidence does not satisfy the required standard of proof to make an adverse finding that the CO used the alleged words (or a similar threat or direction) to the effect that participation in the trial was required in order to deploy to East Timor.

FINDING 35: MAJ McCarthy’s allegation, that in an address to the battalion concerning the anti-malarial drug trial, CO 1 RAR indicated that those who did not volunteer to participate in the trial would be excluded from the deployment, is not substantiated.

RECOMMENDATION 3: The ready acceptance by soldiers of advice or encouragement provided to them by military persons in authority, combined with a potential belief that participation in the trial was expected is an issue worthy of further consideration in the conduct of any future medical trials, particularly in the context of a pre-deployment for an overseas operation.
MEFLOQUINE TRIAL

245. The second trial, testing the safety and durability of mefloquine, began in April 2001 with the 4 RAR Battalion Group, as the earlier 1 RAR tafenoquine trial was concluding. The 2 RAR Battalion Group later took part in the mefloquine trial commencing in October 2001. The significant distinction between the mefloquine and earlier tafenoquine trials is that both drugs used in the mefloquine trial were already approved and registered medications with TGA. Doxycycline and mefloquine are normally provided to soldiers through the usual doctor/patient consultation process, and as with most prescription drugs this does not involve signing a written consent form. However, mefloquine was the ADF’s second line anti-malarial preventative medication and therefore not usually prescribed to soldiers in large numbers. Most were prescribed the first line anti-malarial preventative medication, doxycycline.

246. The conduct of a clinical trial gave the soldiers the choice to participate or not and provided a higher level of research through the provision of far more detailed personal information by participants than would be provided where the drug was prescribed in the usual manner. So the trial was voluntary and an informed consent process needed to be followed for those taking mefloquine.

Informed consent

247. COL from AMI was the primary developer of the mefloquine trial and the Principal Investigator for the 4 RAR deployment. He also attended many of the pre-deployment briefings for 2 RAR, but was not the Principal Investigator for that trial. COL indicated that although command were keen to use a weekly drug, it was made clear from the initial briefing to CO 4 RAR that the trial was voluntary. He confirmed that he was not aware of any directions or threats against soldiers by the chain of command that failure to participate would result in non-deployment, and said:

No, despite the origin of the request for a weekly [drug]..., at no time at the battalion did I witness any evidence of a directive. In fact there was a lot of effort made to indicate that this was not a directive, but the operational orders required the use of an anti-malarial for good reason. People understood that. But there was no directive that it had to be this anti-malarial. If they chose not to be a part of this then they...would take the anti-malarials that Defence policy would drive.

COL had a similar view on the later 2 RAR mefloquine trial, namely, it was also entirely voluntary and there was not directive from command to the contrary.

Recruitment process and medical briefings

248. The recruitment and medical briefing phase followed a similar process to that discussed for the earlier 1 RAR tafenoquine trial, noting that this trial did not involve a new and unregistered drug. There were three types of medical briefings. The first one was the usual briefing given to the soldiers in groups ranging from platoon to company size and dealt with the anti-malarial drug trial and the information contained in the (yet to be given out) trial participation consent form (which included voluntariness and side effects). Secondly, COL provided briefings for families
(partners and soldiers) in the evening so any issues concerning the trial and mefloquine could be discussed. These were well attended and many questions asked. He commented,

*I had some really intelligent questions asked by wives, particularly, who had done internet searches and were well aware of the lay information that was available about Mefloquine, and so were asking sensible questions about why we would do this and expressing their concerns.*

249. The third briefing was the normal confidential doctor/patient consultation where mefloquine would be prescribed. This usually occurred after the consent form was signed, but there was discussion of all the information in the consent form (including about side effects), and whether the drug was suitable for that soldier based on his medical history. At that stage a soldier could still decide whether or not he wanted to participate in the trial. If the soldier did not wish to continue, then doxycycline would be prescribed.

250. COL [redacted] recalled that he would normally say to the soldier:

*You may find it quite strange that we are actually giving you a choice, but under no circumstances are you absolutely required to join this or to take this drug and moreover if you choose not to you can take the regular drug, Doxycycline, and we can test to see whether you're happy with that*. But I then usually go on to identify that, "In no way will this compromise the health care you're provided or your opportunity to deploy".

251. There was also an opportunity for a person to withdraw from the trial at any time. A loading dose was given on three occasions over three days prior to deployment. This was done to determine the dose’s predictive value of likely adverse reactions to the drug. COL [redacted] noted, *Assuming that he [a soldier] had consented to the study—and then gone onto Mefloquine and then taken a loading dose, he would’ve still had another [medical] consultation to determine, before we went away, whether he was happy with the drug.*

**Consent form**

252. The consent form used for this trial was two pages in length and in a similar format to the one used for the 1 RAR tafenoquine trial. As it was an open and not a blind trial, and it dealt with mefloquine only (not a new drug), it did not go into as much information about the trial process as in the 1 RAR tafenoquine trial consent form. COL [redacted] stated the *usual practice, [was] to require consent forms to be given [out] and then a period of time made available for the individual to digest the information. So typically consent forms are provided ahead of time*, often before or at the briefs, and returned later.

253. The information provided in the consent form concerning the ‘Risks/Discomforts’ (side effects) of mefloquine was comprehensive going beyond what was in the CMI provided to patients, and took on a statistical format similar to that used in the approved 1998 Lariam product information form. It comprised a list of events with a chance of occurrence of over one per cent (common), such as gastrointestinal issues, dreams, dizziness, loss of balance and headache; those less than one per cent (uncommon events), such as anxiety, confusion, depression, fever, chills, ringing in the ears and paranoid reactions; and those less than 0.1 per cent (rare events) such as brain injury, psychotic events and severe hypersensitivity reactions in the skin.
254. COL commented, '... you have to balance the size of a consent and information sheet and the amount of information that an individual can actually process' ...and 'it's not the usual practice to put in large lists of rare adverse events'. However, he explained that unlike the earlier 1 RAR trial, which was testing a new drug tafenoquine, this trial was primarily testing mefloquine for safety and tolerability in comparison to doxycycline, so it was important to be open and detail all possible side effects. He went on to say:

*When we went to the subsequent study that focussed in an un-blinded fashion on Mefloquine, we provided additional information really because it was quite well known that Mefloquine had developed this darker, sinister profile that I think was largely unwarranted. But it certainly had been demonised as the drug that caused all these sorts of trouble. And so we felt that it was appropriate to provide the information to people that was objective. People that are making a decision about whether or not they would use this medication to prevent them getting malaria while they're deployed to Timor, we felt that for them to make that decision in the context of the information that was available in the lay media about Mefloquine, that providing more objective accurate information was appropriate. And can I say that we went beyond just writing it in the consent form. We provided information evenings and sessions.*

255. The ADMEC meeting minutes of 26 February 2001 have been raised in the media (23 December 2015) as evidence Defence knew of serious adverse effects of mefloquine before the trial, and by implication those raised by MAJ McCarthy (mefloquine neurotoxicity), thereby inferring the trials should not have gone ahead. The full ADMEC minute, including MAJ explanation states:

*[the trial protocol] caused considerable debate when it became apparent that Mefloquine had potentially serious side effects of which ADMEC had been previously unaware. In particular, side effects of depression and psychosis caused considerable concern to Committee, especially were they to occur in deployed troops. Major emphasised that this prospective study was scientifically necessary in order to accurately categorise the side effect profile of the drug, which is currently the [ADF's] second line treatment of choice for malaria. He also explained that by far the majority of side effects manifest within the first four doses of the drug, which will be administered within Australia.*

256. COL confirmed new side effects had not been uncovered since the earlier 2000 trial, and the ADMEC committee's concerns were about the protocol reflecting all the possible serious side effects contained in the product information, some of which they were not aware of. For the reasons explained in the preceding paragraph, COL believed it was necessary to be open about the possible side effects of mefloquine, including rare events.

257. The consent forms were not signed in front of the investigator nor witnessed as they were for the 1 RAR tafenoquine trial. This was not required by ADHREC and in COL view not necessary. He commented: 'the level of confirmation required of an informed consent is much less when you were using exclusively approved medications within their indication.' COL indicated consent forms were effectively confirmation of the information already passed verbally to the soldiers from the group briefing and during the doctor patient consultations. He agreed soldiers may not read the consent forms in detail and this reinforced the importance of
the verbal briefing process. Where the forms were too detailed to read (or not read at all) ‘the failsafe is that they have a briefing, a verbal briefing, and then they have this one-on-one doctor/patient prescription where the information is gone through again anyway.’

Dosage of mefloquine

258. Two matters arose during the course of the Inquiry concerning the dosage of mefloquine and the length of time it should be taken. In respect of the dosage, mefloquine is given as a loading dose on three occasions in the week before deployment. This loading dose is necessary to reach the appropriate level of protection when going into a high risk malaria area. (This was also done with tafenoquine in the 1 RAR trial). Once in location (East Timor), the dose reverts back to being taken once weekly. An additional advantage of the loading dose studied and demonstrated in both trials was any adverse effects of the drug had a greater chance of becoming apparent during that phase prior to deployment. The loading dosage procedure is not addressed in the Australian CMI for Lariam (mefloquine), but is recognised practice. For example, the New Zealand CMI for Lariam does provide for a loading dose in these circumstances.

259. Mefloquine is normally taken for up to three months. When the three-month period is reached that does not mean a user must stop taking the drug. The Lariam CMI clearly states that a user should not stop taking the drug, but consult with their doctor. After that consultation the doctor may continue to prescribe mefloquine or change the prescription to another anti-malarial. The ADF policy is to prescribe the drug for six months for soldiers on deployment and then conduct a review, although most deployments are for six months or less.

Complaint about 2 RAR and 4 RAR mefloquine trials

260. Although MAJ McCarthy’s principal complaint concerned the voluntary nature of the 1 RAR tafenoquine trial, on 01 May 2016 he provided the Inquiry with a list of 10 witnesses as evidence of what he termed ‘2 RAR coercion’, [meaning] subjects informed by various members of the chain of command that mefloquine was the only drug available and/or if they did not participate in the trial they would be excluded from the deployment’. On the same day, MAJ McCarthy also claimed: ‘he had spoken to numerous veterans on the 4 RAR mefloquine trial who state that although they weren’t coerced, they also weren’t properly informed of the risks associated with taking mefloquine.’ He advised that the best person to speak to about 4 RAR was Mr

2 RAR witnesses

261. The Inquiry contacted the ten 2 RAR witnesses identified by MAJ McCarthy and received replies of assistance from half, and subsequently interviewed four.

Mr

262. The first Mr was a member of 2 RAR in 2001. He had previously deployed to East Timor in 1999 with INTERFET when he was a non-Infantry Corps member of 2 RAR. His evidence was summarised in his initial e-mail of 09 May 2016 to the Inquiry, where he said, ‘I was never forced into signing nor threatened with non deployment as COA [course of action] if I didn’t sign the waiver. I specifically remember the day we were outside D Coy, [with] the malaria team.’
263. At interview, Mr advised that after leaving the Army in 2004 he joined the and deployed overseas. He was medically retired from the in 2013 with accepted conditions from both DVA and the . He suffers seizures from what is known as ‘conversion disorder’. When he returned from East Timor Mr stated he suffered from depression, could not sleep, and had some violent episodes but at the time (and still) does not know whether these were caused by mefloquine. He was diagnosed with PTSD (unbeknown to the after he left the Army in 2005.

264. At interview Mr confirmed from his perspective the trial was completely voluntary with no threat of non-deployment from within the company, or from the CO, if he did not participate, nor detriment to his career. He could not comment on the other 2 RAR companies. His memory of events 15 years ago was poor. However, he confirmed, ‘We got to the outside of... and there was shitloads [sic] of medics and what I know now, they were from the bloody malaria institute. But they gave us a briefing on mefloquine and that’s when we signed the waiver. That day.’ Mr indicated that although he did receive a briefing he could not remember anything much about it. He said ‘the thing that caught my attention was ... we only have to take it once a week. That’s all right.’

265. Mr said, ‘before you go on deployment, especially when you do all your stuff, you’re going through the good old PDA, pre-deployment anxiety, and you’ll do anything and you don’t really give a [damn]. You just want it to happen. He indicated everyone was keen to deploy and get over there and that there were many pre-deployment briefs ‘as you know, it’s like getting a hose shoved down your mouth and turned on’. So although Mr did not read the consent form and signed it anyway, he agreed he was given information on it.

266. Mr says he became aware of the issue when he ‘saw the mefloquine Facebook page. This Australian Veterans’ Mefloquine page and I had a look. And then I actually spoke with McCarthy and I said “I have PTSD, depression, anxiety, grog and conversion disorder where I have seizures.” And I had already seen a neurologist about my seizures and it’s been confirmed, it’s conversion disorder.’

267. In conclusion, Mr stated, ‘Well look, I just want to say that, I mean, look going by all the protocols and the ethics, they did it correctly to us in .’

268. CPL was interviewed on 12 May 2016. At this time, CPL was discharging from the Army. Prior to deployment in 2001, he had previously taken an anti-malarial medication (doxycycline) on exercise and had suffered from ‘doxy dreams’. CPL was the at 2 RAR. He recalls being told on parade by his OC (MAJ about the voluntary trial, but later being told by company staff (he could not remember ranks, names or picture faces) words to the effect that he had to participate in the trial if he wanted to deploy and that the advice came from the CO. After further discussion of the matter CPL indicated these comments came from the upstairs office in the . He believed this happened after the medical briefs.
CPL had a vague memory of a medical briefing by the RMO, not AMI, but stated the briefing discussed the drug mefloquine and its side effects. He indicated the medical briefing said the trial was voluntary. He explained his understanding of voluntary from the medical briefing was, 'you didn't have to participate, you'd be given different malarial drugs if you didn't want to participate.'

A consent form was signed by CPL around September 2001 after the medical briefing and handed back to the medical officer. Having now seen and read the consent form given to him by the Inquiry, CPL had a vague memory that the information in it was explained to him by the medical officer. In the end he 'had no problems with actually participating at the time.' On reflection CPL acknowledged the comments he heard from upstairs at the Coy HQ about participating in the trial to deploy were heard after the medical briefing and his signing the consent form.

CPL indicated he suffered some gastrointestinal side effects from the mefloquine loading dose before deployment (but no dreams like he had with doxycycline), but when he went to the weekly dose overseas he did not experience any further difficulties. He did not recall any of his mates having any serious side effects from taking mefloquine. CPL said the medical support provided was good. Upon return to Australia, ceasing mefloquine and after going through the eradication phase he did not suffer any visible effects of mefloquine, such as getting sick.

After deploying to the Solomon Islands in 2003, CPL returned to Australia and was diagnosed with depression in 2004. He discharged voluntarily in 2006 and still suffers from depression but it is under control. He has highlighted his mefloquine use to see 'whether that could help give a medical practitioner another angle of trying to work out why [he still suffers from depression].'

Mr was posted to 2 RAR from 1997 until 2000. He discharged from the Army in 2006 and joined the where he still is. Then-PTE first deployed to East Timor in 1999 with 2 RAR as part of INTERFET and was on doxycycline anti-malarial medication. He remembered the malaria problems his battalion had faced on that deployment. PTE deployed with 2 RAR again in October 2001.

In an email sent to the Inquiry on 13 May 2016, Mr raised two issues. The first concerned voluntary participation in the trial. He said:

\[\text{During this time I spent time in and . I recall that during the lead up to our deployment and the formation of the we had a Battalion parade. I think it was some what informal ie a hollow square near the mess. During this time we were instructed by the CO Lt Col that we would be partaking in a trial for a new malaria drug and that more information would be given to us closer to our deployment date. It was also said at the time if you didn't take the new drug you would not be deploying with the Battalion.}\]

At interview Mr initially said to the best of his memory the CO actually said those words. After further questioning and being informed what other witnesses had said Mr conceded that he had no direct memory of the CO
saying those specific words and he agreed that perhaps it was something he had inferred from strong encouragement to participate in the trial. He commented that he was a young private solder at the time and his memory of events 15 years ago was not good. He said:

*Yes. There probably - there was a lot of encouragement to participate. Whether or not I inferred that what was said - and looking back, maybe it was - maybe that was what I - the inference that I drew, “If you don’t take it, you don’t go,” but I do recall that we were told - whether it was at a company parade or within our platoon - “If you don't take it you don’t go,” because one of the guys questioned ... I do recall someone - I don't know who - questioning the - not the trial but questioning taking the drugs and what we had to do, or the consent forms and waivers, and what happens if we didn’t want to do it, and whether it was the NCOs taking the thing into their own hands and made the comment “If you don’t take it you don’t go” - but I do remember hearing someone say, “If you don’t take it, you don’t go.”.*

276. The second issue in Mr’s email concerned the medical briefings and the consent form where he said:

*Some days or a week later held a parade where we were told to collect and sign pre-deployment form. Most of soldiers signed them with out reading them. These were in fact the consent forms for the Lariam trial. A few soldiers questioned the drug and were told it’s better than doxy and you only take it once a week.*

277. At interview Mr indicated he had no memory of a medical briefing on the trial, but accepted there would have been one as part of the ‘bull ring rotation’ of briefings for pre-deployment. While he knew he was on mefloquine which he inferred was an experimental drug because of the trial, he does not remember any information being provided such as about side effects only that it was taken once a week.

278. The consent form was one of many forms Mr recalls from the deployment, but he can not remember it specifically. He just signed it and gave it back with the rest. He did not remember any briefing on the issues in the form including the voluntary nature of the trial; or an individual consultation with a doctor where he was prescribed the drug and the loading dose explained, although he says it may have a happened.

279. Mr did not recall having any side effects from the initial loading dose prior to deployment. In East Timor he had no side effects after taking the mefloquine but remembers that the day or two before he was due to take it, he suffered withdrawal type symptoms from not having had the drug. This made him irritable and angry, which went away after taking his next weekly dose. He did not suffer any gastrointestinal problems but had vivid dreams. These matters were not raised with the medical staff. Upon his return to Australia and after ceasing the medication the now CPL developed malaria, which required his admission to the military medical facility in Lavarack Barracks. He spent four months on convalescence leave before he could return to work.

280. Mr concluded by indicating he was not aware of any ongoing issues from his use of mefloquine or from his bout of malaria. He still gets ringing in ears which maybe related. Mr became interested in the mefloquine issue after reading the Facebook page, but had no qualms with the Army and the way he was treated and did not leave the Army disgruntled.
LTCOL

281. The then-MAJ was the prior to, and during the first part of the deployment of 2 RAR to East Timor in October 2001. He was in the second half of the deployment. MAJ left the permanent Army in 2009 at the rank of lieutenant colonel, and is now in the ARES performing duty at . His civilian occupation is the working in the . LTCOL email of 10 May 2016 to the Inquiry summarises his view on the issue of informed consent:

My recollection is that while there was no compulsion to participate in the trial it was very strongly encouraged for reasons of expedience and simplicity of administration. I also recall that there was some advice provided in relation to possible deleterious side effects.

LTCOL was interviewed on 13 May 2016. He indicated he had previously deployed to East Timor in 1999/2000 as part of the Deployable Joint Force Headquarters as well as to Somalia in 1993 as part of 1 RAR. LTCOL evidence at interview is summarised as follows:

a. The issue of malaria during INTERFET was a concern to command, and there was a need for better prevention measures in future deployments.

b. During an Orders Group with the CO, he learnt of the trial involving mefloquine, which then-MAJ knew as Lariam. The opportunity to use a different malaria prophylaxis was welcomed by then-MAJ.

c. The medical briefing was done by the battalion RMO and the AMI staff. The trial of mefloquine, which he knew was an already approved and used anti-malarial medication, was discussed in detail. He recalls that the advantages of a weekly taken drug and its possible adverse side effects were explained. He was satisfied the possible side effects were outweighed by the risk of contracting malaria.

d. Participation in the trial was explained during the brief as voluntary and participation was not required for deployment. He did not, at the time, have any concerns about the voluntary nature of the trial.

e. The consent form was handed out that night after the medical briefing. Having now looked at the form, he recalls the detailed information it contained on the possible side effects of Lariam had been briefed by the medical staff. At the time of signing the form, he was quite comfortable with being a participant in the trial. He acknowledged the trial was one small part of a busy pre-deployment schedule and he was not surprised soldiers may not read the consent form before signing it.

f. He remembers there was a lot of discussion about the possible side effects at the medical briefing and afterwards amongst the soldiers. From his perspective, the adverse effects were a low risk and acceptable when compared to contracting malaria. He and many of the senior NCOs had previously seen the effects of malaria first hand in East Timor and elsewhere.
The ease of compliance and the logistic advantages of a weekly taken drug were promoted by the medical staff, although he was conscious of the risks and believed they had been adequately explained. However, he agreed most soldiers would trust the Army only to give them safe drugs, and in this case, the drug being trialled was an approved anti-malarial medication already used by Defence.

When the evidence of Mr [redacted] that ‘if you don’t take it, you don’t go’ was put to him, LTCOL [redacted] did not recall anyone in his company (including himself) saying any words to that effect. Furthermore, he did not recall there being any directive by the CO being given on parade or elsewhere indicating ‘if you didn’t take the new drug you would not be deploying with the battalion.’ LTCOL [redacted] commented that the CO acted very ethically in everything he saw of him, and agreed a direction that participation in the voluntary trial was required would have been out of character for him.

LTCOL [redacted] was not aware of any rumours from his [redacted] that participation in the trial was required for deployment, as raised by CPL [redacted] the [redacted]. He did not recall any official information passed down from the upstairs office of his HQ that the trial was not voluntary.

In his opinion, there was very strong encouragement to participate in the trial for reasons of better protection and administrative expediency. He believed most soldiers were comfortable with participating in the trial.

The trial was well run by AMI, and appropriate medical support provided. He suffered no side effects after the initial loading dose in Townville, nor on deployment in East Timor. Some members of his company suffered from adverse Lariam dreams on deployment. There was one NCO on mefloquine who had a psychotic episode which apparently stopped soon after changing his anti-malarial medication.

On return to Australia, he recalled there was a discussion about the battalion having very little malaria or dengue and that the preventative measures, including the weekly medication, had been successful. Although a number of soldiers, including himself, have had some depressive episodes and other medical conditions in the 15 years since taking mefloquine, he commented it would be very premature to attribute any of these conditions to any of the anti-malarial drugs.

LTCOL [redacted] indicated he became aware of the mefloquine issue through social media and newspaper articles.

4 RAR witnesses

Mr [redacted]

283. On 03 May 2016 Mr [redacted] lodged a submission with IGADF concerning his participation in the 4 RAR mefloquine trial in 2001. In his
284. Mr enlisted in the Australian Army in 1989 following a short engagement in the . After discharging in the mid-1990s he re-joined in 1999 and was posted to 4 RAR. Then-PTE deployed to East Timor in 2001 and later to the Solomon Islands in 2003. Following that deployment, he transferred to and took discharge from the permanent Army in 2005. In 2008 he worked as an employee in the section in Canberra. Mr left in 2012 and in the same year commenced employment with the working in in the area of mental health, alcohol and other drugs.

285. When asked how he knew MAJ Stuart McCarthy, Mr said they met through Facebook and he was asked by MAJ McCarthy for assistance with dealing with the media and for some media contacts. He was able to provide that assistance to MAJ McCarthy.

286. Mr memory of events surrounding his deployment to East Timor 15 years ago is by his own admission very poor. He recalled receiving a suite of pre-deployment briefings during which he probably found out about the mefloquine or Lariam trial, although he has no memory of any of these briefings. In particular, Mr has no recollection of receiving a medical briefing about the trial by the RMO or AMI staff, but accepts he would have received one. He does not believe there was any issue about the voluntary nature of the trial.

287. Although he has now seen the consent form, which he received with his medical documents concerning the trial from AMI (and also from the Inquiry), this did not trigger any memory of a group briefing on the content of the consent form, or being individually spoken to by a medical officer prescribing the drug (Lariam) to him. He had no knowledge of any potential side effects of mefloquine.

288. Mr was questioned about the circumstances of receiving the consent form in the near dark. He did not read it but simply signed and returned it. He does not recall the names of any of the persons involved in this process. He remembers thinking at the time the trial must be ‘real’ as they were asking for his consent, which meant to him there must be some sort of risk involved. He could not believe he was being asked to sign the form uninformed and literally ‘in the dark’ and regretted not speaking up at the time. However, he stated, ‘I think
everyone just wanted to sign them, get out of there, and I think because the OC, because it was a battalion thing, I think we just trusted, put our faith in our leaders.'

289. Mr reiterated he had no memory of the medical briefings raising the issues in the consent form. However, like other members of the battalion, he was so keen to deploy that even if he had read the consent form and known the side effects, he still would have signed. He said ‘It’s all down to, you just trust, you’re part of the team, and why would anybody take a risk like this with our health? We trusted. We just went along with it. ...[and]... If it was good enough for my CO and was good enough for my OC, it was good enough for me’.

290. Mr had no memory of being given a loading dose of mefloquine by medical staff prior to deployment. He believes he took the drug every Wednesday when in East Timor and recalls experiencing Lariam dreams that night, but can not remember whether the dreams lasted for the whole deployment. On return to Australia, he also does not recall having any side effects after ceasing the drug and going through the eradication process. Mr does believe his use of mefloquine may have affected his memory.

291. While Mr indicated he had ‘selective memory’ of his deployment to East Timor in 2001, the signing of the consent form in the dark was memorable to him because he thought it was ‘dumb’. At the time he did not raise the issue because he did not think it was a ‘big deal’. But now he thought was the right time to raise the issue because he could see the ‘momentum’ gathering about mefloquine.

292. When Mr returned from East Timor, he later suffered from anxiety and depression and sought medical assistance. He had a further deployment to the Solomon Islands before transferring to the in 2004 and leaving the permanent Army in 2005. After recently reading about and researching the mefloquine issue, Mr would like to know whether his depression and other associated medical issues may have been caused or contributed to by his use of mefloquine.

293. COL the Principal Investigator for the 4 RAR trial, was asked about Mr concerning the circumstances of the signing of the consent form. Although not aware of the case, the AMI team did provide information sessions to soldiers in the field. However, the usual practice was to hand out the consent forms after the medical briefing to be handed back at a later time. If the soldier chose to sign there and then, that was their prerogative. COL commented there was still the opportunity at a later time for the soldier to have the consultation with a doctor regarding the prescription for mefloquine, and then to be seen a further time to determine whether or not that mefloquine was suitable for them. At both of these occasions the soldier would have been given the opportunity to withdraw from the trial, and to ask further questions.

294. COL agreed the signing of the consent form was confirming information that had already been provided about the medication and the nature of the trial. He was not surprised that soldiers may not read a consent form so it was important not to have a too detailed form, and also to ensure the information was passed verbally to them through briefings and consultations.
Then-MAJ 4 RAR at the time, was identified by Mr. as a person who had recently confirmed Mr. version of events surrounding the signing of the consent form. Mr. explained that MAJ had been medically discharged from the Army shortly after the deployment because of a seizure, which, Mr. said, potentially may have been caused by mefloquine. Mr. is now a ‘Soldier On’. The Inquiry initially made contact with Mr. by email and he agreed to be interviewed. Subsequent attempts to contact Mr. by email, telephone (voicemail message left) and SMS text were unsuccessful and the Inquiry was unable to gather any evidence from him.

Analysis and assessment of evidence (Mefloquine trial)

The evidence from COL the principal AMI investigator, of the consent process followed during the 4 RAR and the 2 RAR mefloquine trials is not directly challenged by evidence from any witness. The Inquiry is satisfied that during the medical briefing and the subsequent doctor/participant consultation, soldiers were informed of the potential side effects of mefloquine, an already approved and registered drug; that the trials were voluntary and would have no effect on their deployment or career if they did not participate; and that they could withdraw at any time. The Inquiry assesses during briefings the Principal Investigator not only emphasised that the soldier had a choice whether to participate or not, but he also had ample opportunity to withdraw from the trial. This could (and did) occur after the consent form had been completed and during the doctor/participant consultation where the drug was prescribed, or after the loading dose was administered in Australia when the soldier saw a medical officer for a second time. The Inquiry accepts it was not a requirement under the NHMRC guidelines for the consent form to be witnessed or signed in the presence of a medical investigator, and the purpose of the consent form was to confirm in writing information already passed to participants.

Mefloquine and doxycycline are both registered drugs in Australia. The Inquiry is satisfied information provided in the consent form concerning the potential side effects of mefloquine was comprehensive going beyond that contained in the 1998 Lariam Consumer Medicine Information (CMI) normally provided to patients and was consistent with the more detailed 1998 Lariam product information. The Inquiry accepts this was done because unlike the 1 RAR trial, which was testing a new drug tafenoquine, this trial was testing mefloquine (in large numbers) for safety and tolerability, so it was important to be open and detail all possible side effects, in order to avoid any claims that soldiers were not adequately informed of all potential risks and to address some of the myths about mefloquine.

As was the case with the 1 RAR trial, MAJ McCarthy’s general complaint in relation to the 2 RAR and 4 RAR trials is the failure of the AMI investigators to ensure trial participants were informed of the foreseeable likelihood of mefloquine neurotoxicity (permanent brain or CNS injury). Mefloquine neurotoxicity was not recognised by Defence health authorities or by the AMI investigators as a potential side effect of mefloquine use. The trial consent form was consistent with the 1998 product information and consumer medicine information, which do not recognise and include mefloquine neurotoxicity as a possible side effect of mefloquine use. Accordingly, the AMI investigators did not act unethically or unreasonably by not disclosing mefloquine neurotoxicity as a potential (or, as MAJ McCarthy has asserted, foreseeably likely) side effect to participants in medical briefings, or including it in the trial consent form.
2 RAR trial

299. MAJ McCarthy's further complaint concerning the 2 RAR trial is one of 'coercion, [meaning] subjects informed by various members of the chain of command that mefloquine was the only drug available and/or if they did not participate in the trial they would be excluded from the deployment'. The Inquiry assesses that the evidence from the four 2 RAR witnesses (provided by MAJ McCarthy), who all took mefloquine, does not support this complaint. As regards the first aspect of the complaint, no evidence was provided by the four 2 RAR witnesses that soldiers were informed that mefloquine was the only drug available.

300. The first witness interviewed from 2 RAR, former PTE was adamant the trial was completely voluntary with no threat of non-deployment from within the company, or from the CO, if he did not participate, or there would be any detriment to his career. He also received a medical briefing on the side effects of mefloquine and happily signed the consent form, albeit he did not read it. Mr is suffering from depression and PTSD, but does not blame the conduct of the trial, including the informed consent process, for his illness.

301. The 2 RAR (then-MAJ) also indicated that the trial was voluntary from both a medical and command perspective and he was briefed on the potential side effects of mefloquine. At interview, LTCOL added that although participation in the trial was not required for deployment, there was encouragement to take part because of the perceived benefits. He was happy to participate because he had deployed to East Timor with INTERFET and had seen the malaria problems first hand. He also saw the opportunity to try a different drug taken once weekly as a positive initiative. LTCOL never heard the CO give an address to the Battalion stating or suggesting participation in the anti-malarial trial was required in order to deploy to East Timor. He added it would have been contradictory to the very ethical manner in which the CO operated to say that a voluntary trial was compulsory in order to deploy. LTCOL gave detailed evidence about the informed consent process including the briefings received. His evidence was considered by the Inquiry to be credible and reliable.

302. Two witnesses from 2 RAR, CPL and Mr initially were of the belief the 2 RAR trial was not voluntary but during their evidence accepted that it was, from both a command and medical perspective. CPL had a poor memory of events surrounding the drug trial. He based his belief the trial was not voluntary on rumours coming out of the where he worked as a clerk. CPL later acknowledged he had already agreed to participate in the trial having gone through the medical briefs and consent process before he heard the rumours. These rumours were not heard by the then-MAJ and he was unaware of any coercion from his to participate in the trial. CPL is suffering from depression, which first occurred following a subsequent deployment to the Solomon Islands in 2004. CPL has highlighted his mefloquine use as a possible cause of his depression. The Inquiry assesses his evidence as vague in parts and not as reliable as other witnesses. In any event his evidence of rumours does not support an allegation of command coercion to participate in the trial, and did not have any impact on his decision to participate.

303. Mr initially complained by email that his participation in the 2 RAR anti-malarial trial was not voluntary because the CO had said on parade that everyone was taking part and if soldiers did not participate, they would not deploy. At interview he admitted he had no direct
memory of the CO actually saying those words and agreed compulsory participation may have been something he inferred from strong encouragement to participate. Mr acknowledged his memory of events 15 years ago was poor. He had no memory of the medical briefings and any explanation of the potential side effects of mefloquine, or being told the trial was completely voluntary. However, he accepted that this process would have occurred as part of the many pre-deployment briefings. Accordingly, the Inquiry assesses his evidence given at interview as tentative and somewhat unreliable, and not supportive of an allegation of coercion by command to participate in the trial.

304. The Inquiry is satisfied participation in the 2 RAR trial was voluntary, and soldiers were aware it was, and they made an informed decision whether to participate or not. There is no credible evidence of any coercion of soldiers by the CO or others in command to participate in the trial. While there may have been rumours of coercion and encouragement to participate, this did not invalidate the informed consent process. In this trial, as was the case with the earlier 1 RAR trial, there is evidence soldiers did not see the drug trial as a significant event, but one of many pre-deployment matters which had to be completed in order to deploy; and automatically elected to participate, regardless of the informed consent process.

305. As discussed in the 1 RAR trial, the issue of voluntariness in a hierarchical organisation may lead to soldiers participating because they believe it is expected of them or they may be letting down the CO and the team if they do not. In this trial the medical investigators went to some lengths to ensure voluntary participation and offered soldiers the opportunity to withdraw from the trial at various stages.

4 RAR trial

306. Following a later allegation by MAJ McCarthy concerning the informed consent process for the 4 RAR trial, Mr submitted a separate complaint alleging his consent to participate in the 4 RAR mefloquine drug trial was unreasonably and unfairly obtained. Specifically, he alleges he was compelled to sign the trial consent form in almost dark conditions where he could not read it, and therefore, did not know of the risks associated with taking mefloquine. His complaint was not corroborated as the one witness he identified as supporting his version of events, the former OC of the company, was unable to be interviewed.

307. Mr acknowledged his memory is selective and he can only remember signing the consent form and nothing else about the extensive trial consent process, including the medical briefings and the one on one doctor/participant consultation prior to being prescribed the drug. While there is no evidence to contradict Mr version of what happened, according to COL the 4 RAR principal medical investigator, such a process would not have been usual. COL acknowledged that the consent forms may have been handed out in the field, but soldiers were normally not required to return the forms until the next day. He went on to say that a soldier may choose to sign the consent form on the spot without reading it and that was the soldier’s choice.

308. COL indicated from his experience failure to read the consent form was not an uncommon event. In this Inquiry at least one 2 RAR soldier has admitted he did not read the consent form and just signed it. Hence, the importance of the verbal medical brief and the doctor/participant consultation, where the side effects of the drug were discussed and explained in a
manner comprehensible to the soldier. The Inquiry assesses the evidence indicates Mr. would have received the medical briefing and must have undergone the required doctor/participant consultation, prior to the drug being prescribed for him. Therefore, the Inquiry is satisfied Mr. would have participated in, and continued, with the trial fully aware of the potential side effects of mefloquine, knowing it was voluntary and he could withdraw any time (and continue on doxycycline) without jeopardising his deployment.

309. Mr. evidence of his disbelief—about being asked to sign a consent form in the dark in the field for a drug trial in circumstances in which he was uninformed about the trial and the side effects of mefloquine—is not credible given that he accepts that he would have attended medical briefings where information about the trial including potential side effects would have been explained to him. Based on his own evidence the reality appears to be that he signed the consent form because it was a battalion or team thing to do and he trusted his leaders to only provide a drug that was safe. He indicates that even if he had read the consent form and knew of the side effects he would have signed it anyway because, like other 4 RAR members, he was very keen to deploy and if it was good enough for the CO it was good enough for him.

310. Mr. comment about his lack of knowledge of the side effects of mefloquine appears to be predicated on information about the permanent neurotoxic side effects raised by MAJ McCarthy on Facebook and in the media and from his own research; and not on information he would have received during the trial, which did not address mefloquine neurotoxicity. Mr. has suffered anxiety and depression and wants to know whether mefloquine could be the cause.

311. The Inquiry assesses that Mr. consent was not unreasonably and unfairly obtained. It is very likely he was provided with sufficient information about the voluntary nature of the trial and the potential side effects of mefloquine by COL who undertook the 4 RAR medical briefings, and this should have allowed him to make an informed decision whether to participate or not. The voluntary nature of the trial and the potential side effects would have been reinforced at the mandatory doctor/participant consultation where mefloquine was prescribed to him. Whether he may have received the consent form in the dark and could not read it, or chose not to read it and sign it anyway, does not impact on the information he would have already received and confirmed at a later date. Hence, the Inquiry is satisfied the trial process was conducted in an appropriate manner to ensure that Mr. decision to participate (by signing the form) and to continue to participate after being prescribed mefloquine was based on informed consent.

312. Again, as raised here by Mr. and during consideration of both the 1 RAR and 2 RAR trials, the issue of voluntariness in a hierarchical organisation may lead to soldiers participating because they believe it is expected of them or they may be letting down the CO and the team if they do not participate. While in the 4 RAR trial the medical investigators went to some lengths to ensure voluntary participation, offering soldiers the opportunity to withdraw from the trial at various stages, this may not have impacted on the soldiers’ decision to automatically participate regardless of the informed consent process. As previously stated, this issue is worthy of further consideration in the conduct of any future medical trials, particularly in the context of a pre-deployment for an overseas operation.
Mefloquine trial findings

FINDING 36: Participants in the 4 RAR and 2 RAR mefloquine anti-malarial drug trials received a comprehensive medical briefing, during which they were informed of the side effects of mefloquine, that the trial was completely voluntary, and non-participation would have no effect on deployment or career. These aspects were reinforced at individual doctor/participant consultations when mefloquine was prescribed to the soldiers taking part in the trial. After the loading dose was administered in Australia and prior to deployment, the soldier had a further opportunity to discuss any side effects with a medical officer and to withdraw from the trial.

FINDING 37: Mefloquine is an approved and registered drug in Australia. The information provided in the 4 RAR and 2 RAR trial medical briefings and consent form concerning the potential side effects of mefloquine was comprehensive going beyond that contained in the 1998 Lariam (mefloquine) consumer medicine information normally provided to patients on prescription, and was consistent with the more detailed 1998 Lariam product information. The briefings and consent form provided sufficient relevant information in a form comprehensible to participants, to allow them to make an informed decision whether or not to participate in the trial.

FINDING 38: The AMI investigators in the 4 RAR and 2 RAR trials did not act unethically or unreasonably by not disclosing to trial participants 'mefloquine neurotoxicity' (permanent brain or Central Nervous System injury) as a foreseeable likely side effect of taking mefloquine. The trial consent form was consistent with the 1998 Lariam product and consumer medicine information forms, which do not recognise and include mefloquine neurotoxicity as a possible side effect of mefloquine use. Defence health authorities and the AMI investigators also did not recognise or accept 'mefloquine neurotoxicity' as a possible side effect of taking mefloquine.

FINDING 39: Participation in the 2 RAR anti-malarial drug trial was voluntary, soldiers were aware that it was and they made an informed decision whether to participate or not. There is no credible evidence of any coercion of soldiers by the CO or others in command to participate in the trial. While there may have been rumours of coercion and encouragement to participate, this did not invalidate the informed consent process.

FINDING 40: No evidence was provided that 2 RAR soldiers were informed that mefloquine was the only drug available.

FINDING 41: One former member of 4 RAR submitted a separate complaint to IGADF that his consent to participate in the 4 RAR mefloquine drug trial was unreasonably and unfairly obtained. The allegation was that he had been compelled to sign the trial consent form in the field in almost dark conditions where he could not read it, and therefore did not know of the risks associated with taking mefloquine. In relation to his complaint:

a. It is likely that the former soldier was provided with sufficient information about the voluntary nature of the 4 RAR trial and the potential side effects of mefloquine during the medical briefings, to allow him to make an informed decision whether to participate or not. The voluntary nature of the trial and the potential side effects would have been reinforced at the mandatory doctor/participant consultation where mefloquine was prescribed to him.
b. The former soldier's comment he could not believe he was being asked to sign a consent form in the dark, uninformed about the trial and the side effects of mefloquine suggesting this was the first time he knew that it was a real trial, is not credible, given he accepts he would have received a detailed medical briefing.

c. The former soldier's consent to participate in the 4 RAR mefloquine drug trial was not unreasonably and unfairly obtained. The trial process was conducted in an appropriate manner to ensure the soldier's decision to participate (by signing the form), and to continue to participate after being prescribed mefloquine was based on informed consent. That he may have received the consent form in the dark and could not read it, or chose not to read it and sign it anyway, did not have an impact on the information he would have already received.

FINDING 42: There is evidence that 4 RAR and 2 RAR soldiers did not see the drug trials as a significant event, rather it was one of the many pre-deployment matters that had to be completed in order to deploy; and they automatically decided to participate in the trial regardless of the informed consent process.

FINDING 43: Soldiers were not compelled or coerced by command to participate in the 4 RAR and 2 RAR anti-malarial drug trials and to take mefloquine.

FINDING 44: 4 RAR and 2 RAR trial participants were appropriately informed by the medical investigators, in a manner comprehensible to them, of the potential side effects of mefloquine, and understood that participation in the trial was voluntary without detriment to deployment or future career and they could withdraw any time during the trial.

DIRECTION 3:

Examine MAJ McCarthy's allegation that he was threatened with disciplinary action for expressing concern for individuals allegedly affected by mefloquine and, if so, what was said; who said it and whether this was fair and reasonable in the circumstance.

313. In his submission to IGADF, MAJ McCarthy complains of threats of disciplinary action and intimidation for expressing concern for individuals allegedly affected by mefloquine. While MAJ McCarthy complains generally of being threatened with disciplinary action, three specific incidents were brought to the attention of the Inquiry. The first incident occurred in late March 2015 when MAJ McCarthy complains he was threatened with disciplinary action for seeking appropriate care for personnel affected by mefloquine neurotoxicity; and relates to information he posted on Facebook. The second incident occurred in late August 2015 and is a complaint by MAJ McCarthy of 'intimidation of a witness' by VCDF and senior members of the ADF prior to his appearance at the Senate Inquiry into the mental health of ADF personnel. The third incident occurred in February 2016 resulting in MAJ McCarthy lodging a complaint to IGADF of harassment, threats and intimidation by . Each of these incidents and the resulting complaints is discussed below.
First complaint

314. The background to the first complaint of threatened disciplinary action commences in mid-2014. At that time, MAJ McCarthy submitted a draft paper for publication in the *Australian Army Journal* concerning the effects of mefloquine on Defence members and his desire for an outreach programme for mefloquine affected veterans. The *Australian Army Journal* forwarded the draft paper to the Directorate of Army Health for review. As a part of that review, then-_________ was asked for his comments which he provided to AHQ with the advice that MAJ McCarthy should engage with the AMI. MAJ McCarthy was not aware of comments at the time.

315. At the end of 2014, _______ attended an _______ in the United States. One of the presentations was by Doctor _______ and was on mefloquine toxicity. _______ had been following the debate on mefloquine and at the conclusion of the presentation spoke with _______ about the issue, and upon his return to Australia continued discussion with _______ via email. Essentially _______ was seeking hard evidence on the new 'mefloquine toxicity' syndrome and its alleged permanent or long term effects, which were claimed to cause chronic mental illnesses and depression. If there was any new evidence concerning mefloquine, _______ was prepared to take the matter to the Repatriation Medical Authority (RMA) for their consideration. (The RMA is an independent, statutory medical authority who make determinations (statement of principles), based on sound medical and scientific evidence, for any disease, injury or death that could be related to eligible military service.)

316. During interview _______ commented: ‘... the vast majority of _______ research is opinions. So he writes a paper about what is plausible and he's actually got no clinical research to back it up’. _______ was of the view that in time this clinical research based evidence will be become available from peer reviewed research studies, saying ‘we must be patient and not be too quick to dismiss the strength of the anecdotal, case series, and biological evidence in favor of [my] hypothesis [about mefloquine neurotoxicity]’.

317. During late 2014 and early 2015 MAJ McCarthy had a number of discussions with _______ about mefloquine neurotoxicity. When MAJ McCarthy was informed by _______ that an ADF officer had attended the _______ , he sought to make contact with the officer through the Conference co-ordinator. Subsequently MAJ McCarthy was contacted by _______ (by email), and MAJ McCarthy forwarded his research paper to _______ proposing an outreach program for ADF veterans affected by mefloquine neurotoxicity, to him. _______ had already seen the paper, a fact he later disclosed to MAJ McCarthy. The pair had a telephone conversation on 03 February 2016 about MAJ McCarthy’s view on the use of mefloquine in the ADF based on his own experiences and on his own research. MAJ McCarthy advised the Inquiry the outcome of the telephone conversation with _______ was that ‘... we basically had a massive disagreement. It became argumentative, so I just hung up on him’.

318. After the telephone call ended abruptly _______ wrote to MAJ McCarthy to try and assist him with a way forward for his issues. The email correspondence between the two officers indicates MAJ McCarthy was frustrated that _______ did not agree with establishing an outreach program for veterans and Defence members who had been prescribed mefloquine and, in MAJ McCarthy’s view, would not recognise that mefloquine was neurotoxic causing long term
harm to veterans and Defence members. MAJ McCarthy concluded the email discussion with ‘Thanks for your time. The ADF administered thousands of soldiers with a neurotoxin, causing long term harm. This is a fact. You refused to even acknowledge this. I will go around you.’

319. At interview, MAJ McCarthy explained he became extremely frustrated no one wanted to accept there are a number of people like him suffering from mefloquine neurotoxicity. He went on to say ‘... so I actually posted that email discussion on my Facebook page... Then a number of people in my Facebook page said, “Look, pull it down. You’re being stupid.”’ Subsequently, MAJ McCarthy indicated he was called into his office at [redacted] and formally counselled with a Record of Conversation being made of the counselling. MAJ McCarthy was informed by his [redacted] of the need to remove the Facebook posting and not to make any further postings. MAJ McCarthy says he was warned not to pursue the outreach programme for veterans up the chain of command, and to pursue only his own medical issues. MAJ McCarthy was told if he contravened his [redacted] directions, as set out in the Record of Conversation, appropriate action (including disciplinary action) would be taken against him. MAJ McCarthy believes this threatened disciplinary action was instigated by [redacted] as a result of their email exchange and telephone conversation in early February 2015 concerning the provision of appropriate care for personnel affected by mefloquine neurotoxicity.

320. At interview [redacted] responded to MAJ McCarthy’s allegation, stating he never threatened or instigated any disciplinary action against MAJ McCarthy. After their last email correspondence in early February 2015, [redacted] did not contact MAJ McCarthy again, and at the time did not refer their discussion to AHQ or anyone else for further action. However, in February and March 2015 [redacted] was involving in drafting responses to a Ministerial submission made by MAJ McCarthy and to matters raised by MAJ McCarthy’s father with the [redacted]. During this period [redacted] first became aware of MAJ McCarthy’s Facebook postings of their email correspondence. [redacted] also told the Inquiry, that as a result of his initial discussion with MAJ McCarthy and concerns about his health, he did raise the matter with the [redacted] who in turn engaged with MAJ McCarthy’s health practitioner to ensure he was being properly cared for.

321. The Inquiry consulted with and interviewed [redacted], MAJ McCarthy’s [redacted] to ascertain whether any disciplinary or administrative action had been contemplated, or instigated, against MAJ McCarthy in early 2015. From oral and documentary evidence received, a timeline of events leading up to HQ 2 Div being made aware of MAJ McCarthy’s Facebook postings was established and is set out below:

a. In January 2015, MAJ McCarthy was posted to HQ 2 Div into the CIMIC (Civil Military Cooperation) branch. [redacted] was his direct subordinate. [redacted] was aware from MAJ McCarthy previous unit’s hand over (on 19 January 2015) that he had been under [redacted] to take up his new posting at HQ 2 Div.

b. MAJ McCarthy was open about his illness and informed his new [redacted] he was overcoming a significant health disorder and was getting better. He went on to explain in detail how his health issues had been caused by the drug mefloquine,
which he was prescribed as part of an ADF trial. MAJ McCarthy also said he had written a paper on the effects of mefloquine use in the ADF. MAJ McCarthy’s primary concern expressed to MAJ McCarthys was that mefloquine had , which was not recognised by the Army. He told LTCOL Smith he was treated for health issues as opposed to which the mefloquine caused.

c. During the next month observed MAJ McCarthy was often late, he was . As a result of his lateness, MAJ McCarthy on 23 February 2015.

d. In the period from 04 February to 12 March 2015, AHQ and JHC dealt with a Ministerial request from MAJ McCarthy through his local Member of Parliament concerning the effects of mefloquine and two letters from .

e. On 24 February 2015, was notified (from within HQ 2 Div) that MAJ McCarthy was planning to go outside the chain of command with letters to the media about mefloquine. had an informal counselling session with MAJ McCarthy and explained the rules about talking to the media. MAJ McCarthy said he understood and had no intention to go outside the chain of command.

f. In early March 2015, MAJ McCarthy was deployed on Exercise BLUE DIAMOND 2015 but was sent home early by as he was ineffective. As a consequence, referred MAJ McCarthy for (health) assessment. The assessment report was received on 23 March 2015 and indicated MAJ McCarthy was not fit for work.

g. On 17 March 2015, MAJ McCarthy sent an information copy of a private (non-Defence) email to in which MAJ McCarthy claimed to have posted material on Facebook concerning . The material comprised the email chain of correspondence between and MAJ McCarthy during the period 27 January and 03 February 2015 concerning mefloquine, and an introductory statement explaining the email chain. advised of the email and at her direction it was forwarded that day to for their attention.

h. The introductory statement to the Facebook posting by MAJ McCarthy commenced by stating, ‘For the senior ADF Officers who visit my page, here is a snapshot of the ADF health system’s criminal negligence in relation to mefloquine and veteran’s mental health.’ It went on to discuss the attached email correspondence between and MAJ McCarthy, indicating responses about his (McCarthy’s) mefloquine paper were ‘dismissive, arrogant [and] condescending.’ was accused of covering up and lying to senior officers about the effects of mefloquine, and conducting one of the ‘infamous 2001-02 Army Malaria Institute mefloquine/tafenoquine trials in East Timor, which poisoned 1100 diggers with a neurotoxicant which gave many if [sic] them permanent brain injuries.'
i. On 20 March 2015, following receipt of MAJ McCarthy’s email to [which regularly monitors social media concerning Defence matters], detected two further Facebook posts by MAJ McCarthy. On 15 March 2015 MAJ McCarthy had posted on his publicly accessible Facebook page comments about [concerning mefloquine]; and on 17 March 2015, a copy of an ‘official use only’ US Army Information Brief on mefloquine. MAJ McCarthy’s Facebook page identified him as a member of the Australian Army.

j. In summary, MAJ McCarthy’s Facebook post of 15 March 2015 accused the Surgeon General ADF of commanding ‘an ADF medical system which: (1) poisoned veterans with a neurotoxic drug causing them permanent brain injury; (2) misdiagnosed and mistreated thousands with psychiatric illnesses when they had permanent brain injury [caused by mefloquine]; (3) bullied the victims while actively trying to cover up the truth [about mefloquine]; (4) lied repeatedly to the senior ADF leadership; [and] (5) colluded with pharmaceutical companies [to hide the effects of mefloquine]. MAJ McCarthy concluded his post by saying this was not ‘merely incompetence but criminal negligence.’ The comments went on to say ‘What has the ADF become? Where is the leadership?’ [and] ‘What a pathetic bunch of cowards.’

k. On 24 March 2015 an email was received by about these inappropriate Facebook posts by MAJ McCarthy. This initiated a telephone conference the following day between about the management of MAJ McCarthy. The outcome of the conference was] that would examine MAJ McCarthy’s medical care and [was] tasked, ‘to counsel him about inappropriate use of social media, in particular his Facebook posts.’

Defence policy

322. The Defence policy covering public comment on social media is contained in DI(G) ADMIN 8-2 Use of social media by Defence personnel. The instruction provides guidance on the use of social media by Defence personnel for the purpose of public engagement and regulates the use of social media by Defence personnel where such use poses a reputational risk to Defence. It is read in conjunction with DI(G) ADMIN 08-1 Public comment and dissemination of official information by Defence personnel, which is the overarching policy instruction.

323. In summary, the applicable policy states a Defence member is not to post official documentation on social media without authority; and secondly, a person identified or identifiable as a Defence member is not to make public comment on social media which may undermine or prejudice Defence’s reputation. This prohibition includes inappropriate comments about policy and other Defence members, which may also be potential breaches of the unacceptable behaviour policy and the Defence Force Discipline Act (DFDA).
Counselling of MAJ McCarthy

324. The counsellor formally counselled MAJ McCarthy concerning his Facebook postings on 26 March 2015. The counselling was summarised in a Record of Conversation (ROC) made by and acknowledged by MAJ McCarthy. The ROC indicates the following matters were covered:

a. Use of Facebook. was advised MAJ McCarthy that his tone and some of his comments in his email exchange with were inappropriate. He indicated that MAJ McCarthy understood this.

b. Use of Facebook. and MAJ McCarthy discussed the posting on Facebook of official email traffic. Additionally, the inappropriate nature of some of the posts and the fact that they were rude, defamatory and insubordinate was highlighted.

c. As a result, a way forward was agreed between and MAJ McCarthy. This consisted of prioritising his personal treatment and welfare and that the unit would conduct an as soon as possible.

d. MAJ McCarthy was directed to cease going outside the chain of command to air his broader concerns about the use of mefloquine (and pursuing the broader outreach program for mefloquine veterans raised by MAJ McCarthy. However, he was free to go outside the chain of command about matters relating to his personal medical treatment and wellbeing.

e. MAJ McCarthy was also directed to cease posting official information on Facebook and to cease posting defamating and/or negative comments about ADF officers on Facebook or any other social media, and to remove all previous Facebook postings.

f. MAJ McCarthy was advised he could continue to use Facebook to pursue his interest about raising awareness about the risks associated with mefloquine. However, in doing so he must not post information that could be considered prejudicial to his position as an officer in the ADF.

g. Finally, 'explained [to MAJ McCarthy] that failure to abide by the directions provided ... above, may result in discipline/administrative action [being taken against him].'

325. At interview confirmed MAJ McCarthy had accepted and acknowledged the counselling and outcomes at the time of the interview, and was subsequently provided with a copy of the ROC by email. However, MAJ McCarthy did not return a signed copy of the ROC to

326. The first was held for MAJ McCarthy on 31 March 2015. In April and May 2015, the focus of HQ 2 Div was on ensuring MAJ McCarthy received the necessary support and medical care for his health. During that time MAJ McCarthy was on informal flexible work arrangements while he On 01 June 2015,
MAJ McCarthy returned to work on a regular basis of three half days a week, and was showing signs of improvement, which continued through the next two months. In August 2015 MAJ McCarthy began working five half days a week. During this period no inappropriate social media postings by MAJ McCarthy were identified by Defence.

Second complaint

327. MAJ McCarthy’s second complaint relates to allegations of intimidation (including an implied threat of disciplinary action) by VCDF and senior members of the ADF prior to his appearance on 01 September 2015 as a witness before the Senate Inquiry into the mental health of ADF personnel. At the Senate Inquiry MAJ McCarthy was to give evidence about what he asserted was the ADF’s unethical use of mefloquine, the failure to acknowledge the alleged permanent neurotoxic effects of the drug, and to reach out to the many veterans allegedly affected by the drug.

328. Background. As previously discussed, in July 2015 MAJ McCarthy lodged a submission with the Senate Inquiry concerning mefloquine use in the ADF, titled ‘Neuropsychiatric Illness, Brain Injury, Neurotoxic Drugs and Moral Injury in ADF Veterans’. He lodged a supplementary submission in August which raised the ADF’s unethical and unlawful use of mefloquine including the conduct of trials by the AMI. In mid August 2015 MAJ McCarthy was approached by a journalist from The Australian newspaper, who had read his Senate submission and now wanted him to ‘go on record’ about mefloquine and his submission. MAJ McCarthy responded to the journalist that while he could use what was on the public record (his Senate submission), he (MAJ McCarthy) was not permitted to go beyond that and he declined to be interviewed. The journalist then wrote an article based on his own research which was published in The Australian on 24 August 2015.

329. The Australian newspaper article of 24 August 2015 was titled ‘ADF “was unethical” in drug trial on troops’, and referred to MAJ McCarthy’s accusations against the ADF, including the following:

a. breaching medical ethics by using 1300 soldiers in the trial of an anti-malarial drug linked to permanent brain injury, a raft of mental health problems and suicide;

b. [conducting a] trial of the drug mefloquine [that] was “manifestly unethical”;

c. medical officers involved in the trial on troops serving in East Timor in 2001 and 2002 were now giving advice in current policy, resulting in a 'culture of denial, deceit and impunity';

d. participants in the trials were not properly informed of the drug’s toxic effects;

e. the commanding officer of one of the units directed that subordinates who did not volunteer would be excluded from the deployment. In effect they were ordered to take a drug which exposed them to permanent neurotoxic brain injury; and

f. MAJ McCarthy took the drug while deployed and suffered from its side effects.
The article then went on to discuss US and British concerns about mefloquine and referred an US expert indicating that "the drug could prove "neurotoxic" for some, which meant it could cause brain injury."

330. Following the publication of the newspaper article, VCDF (Vice Admiral [VADM] RJ Griggs RAN) provided an 'on the record' response via the Defence website titled 'Inaccurate reporting in The Australian. VCDF's response commenced by stating:

Despite a comprehensive response provided to the journalist last week, the article contains a number of errors of fact, unsubstantiated claims and makes a number of allegations about the ethics of a trial conducted by Defence in 2001-2 into the use of the anti-malarial drug 'Mefloquine'. The article quotes Major Stuart McCarthy and an un-named "top" US expert as having accused the ADF of breaching medical ethics.

331. The VCDF response went on to address the claim made in the newspaper article, that the drug trials were conducted unethically and, in particular, the allegations Defence members were ordered to take the drug, mefloquine, and were not informed of its potential side effects. The response also indicated MAJ McCarthy was not a participant in the East Timor drug trials as claimed in the newspaper article.

332. At interview MAJ McCarthy said the first he knew of The Australian article was when he was called into his CO's office about a week before his appearance at the Senate Inquiry, where the CO asked him, 'Why have you been going to the media?', referring to the quotes from MAJ McCarthy contained in The Australian newspaper article. The CO reminded MAJ McCarthy he was not to speak to the media about those issues (as previously raised in the formal counselling of 26 March 2015). MAJ McCarthy explained to the CO he had not approached the media and the quotations and references to him in the newspaper article were taken from his Senate Submission, which seemed to be accepted by the CO.

333. MAJ McCarthy became aware of the 'on the record' response by VCDF later that day or the next morning. At interview MAJ McCarthy expressed the view that the reference in the response to a number of 'unsubstantiated claims' was "a direct attack on [his] credibility ... by the Vice Chief of the Defence Force ... making deliberately deceitful claims about me ...- to which I had zero right of reply.' MAJ McCarthy explained that the claims attributed to him in the newspaper article were all fully substantiated by him in his Senate submission (from which the media article was drawn), and VCDF's statement that a number were unsubstantiated (without referring to that Senate submission) implied MAJ McCarthy's credibility was in question. He found this distressing, particularly as he had no right of reply, and had been confronted by his CO 24 hours before about the newspaper article and warned not to go to the media. MAJ McCarthy asserts that, as he was appearing at the Senate Inquiry about a week later, VCDF's 'on the record' response and being called in by his CO about the newspaper article were designed to intimidate him before his forthcoming appearance at the Senate Inquiry. When questioned further about what he meant by intimidation, MAJ McCarthy said VCDF 'was trying to put me [him] off' appearing before the Senate.
The letter made the following points to demonstrate no improper interference in relation to MAJ McCarthy’s appearance before the Committee.

a. The purpose of the ‘on the record’ response by VCDF on 24 August 2015 was to ensure very serious allegations made in the newspaper article were addressed and not left unanswered in the public domain, particularly the allegations members of the ADF involved in the trials were ordered to take the drug and/or not informed of potential side effects.

b. The response was clearly focused on addressing the inaccurate nature of the article despite a comprehensive response having been provided to the journalist in advance of its publication. The response was not focused on MAJ McCarthy and did not attack his credibility.

c. On 07 September 2015 VCDF had responded to a question from the journalist about McCarthy’s Senate evidence that he was being subjected to intimidation. In the response VCDF highlighted: ‘It was the inaccurate nature of the article that led to the [on the record] response not Major McCarthy’s comments. Major McCarthy is entitled, like any other member of the ADF, to make a private submission to parliamentary inquiries.’

d. The only mentions of MAJ McCarthy in the response were factual in nature, including that he did not participate in the drug trials.

e. In the response VCDF stated: ‘At no stage did I discuss, direct or imply any action against MAJ McCarthy.’ VCDF was personally unaware MAJ McCarthy was giving evidence at the Senate Inquiry in Brisbane.

f. AHQ advised VCDF the discussion with MAJ McCarthy on 24 August 2015 about the Australian newspaper article was initiated by his CO after seeing the article and was not command directed by AHQ.

confirmed he initiated a casual discussion with MAJ McCarthy after the newspaper article of 24 August 2015 was drawn to his attention by COFS at HQ 2 Div. As the article was about MAJ McCarthy’s case 'asked him "Did you write this? We’ve spoken about approaching the media." He [MAJ McCarthy] said, "I didn’t write it. I didn’t give
an interview.” When MAJ McCarthy indicated the information about him (which included direct quotations) was taken from his Senate Inquiry submission and reiterated he had not spoken to a journalist, accepted this and agreed with MAJ McCarthy that he had done nothing wrong. did not discuss MAJ McCarthy’s forthcoming appearance at the Senate Inquiry with him. The ‘on the record’ response of 24 August 2015 issued by VCDF was not raised at the meeting as both and MAJ McCarthy were unaware of it at the time. Subsequently, on 14 September 2015 advised AHQ of these events after they contacted him about MAJ McCarthy’s complaint.

338. In the latter part of 2015 and early 2016, MAJ McCarthy maintained a high profile in mainstream media with a number of newspapers articles featuring his experiences with mefloquine and his concerns about its permanent long term effect on Defence members. Other newspaper articles attacked the AMI anti-malarial drugs trials as being unethically conducted, airing MAJ McCarthy’s view that there was widespread collusion in an attempt to cover up the conduct and findings of the trial. While and HQ 2 Div believed ‘MAJ McCarthy’s media profile and comments were often contrary to Defence policy, it was tolerated because he did not make personal attacks or inappropriate comments’, as he had done in March 2015 for which he was counselled.

339. In early September 2015 MAJ McCarthy proceeded on extended sick leave to South Queensland to be with his family, returning to Sydney in late November. From December 2015 until he was posted back to the South East Queensland area in late April 2016, MAJ McCarthy was on progressive periods each of 28 days’ medical leave. During this period MAJ McCarthy underwent a medical classification review board and is to be medically discharged. According to MAJ McCarthy accepts he should be discharged from the Army, but believes he is being medically misdiagnosed because the ADF health system is not recognising mefloquine as the cause of his permanent brain injury and resulting behaviour (which includes being forgetful, having trouble concentrating and anger management issues). In December 2015, MAJ McCarthy asked that his medical discharge be held in abeyance until he could be properly diagnosed.

Third complaint

340. On 17 February 2016 MAJ McCarthy complained to IGADF of harassment, threats and intimidation by and his superior, . In short the alleged harassment comprised a direction from sent by SMS text on 17 February 2016, to MAJ McCarthy to make a date and time to attend an interview at HQ 2 Div with concerning recent comments MAJ McCarthy had made on social media. In his complaint to IGADF, MAJ McCarthy stated he had already attended an interview on 09 February 2016 (it was in fact on 03 February 2016) with where he was counselled for his recent social media activity Accordingly, MAJ McCarthy believed given his
recent complaints to IGADF and others about threatened disciplinary action and intimidation, a direction to attend an interview with his CO on the same subject, constituted harassment and/or threatening and intimidating behaviour against him.

341. The Inquiry sought clarification of MAJ McCarthy’s complaint as the limited information provided suggested the matter may have been resolved, and because it was not evident why direction to MAJ McCarthy to make an appointment to meet with his CO was harassing or intimidating behaviour. It was also unclear to IGADF whether the interview was for administrative or disciplinary purposes. It was recommended to MAJ McCarthy he comply with the direction to arrange an interview with his CO, but to seek legal advice before he participated. No further information was forthcoming from MAJ McCarthy.

342. The background to this complaint is as follows. On 01 February 2016, it was advised by email of recent social media activity by MAJ McCarthy in late December 2015 and January 2016. It was recognised that MAJ McCarthy was the subject of a long term complex case, Furthermore, MAJ McCarthy had been given significant latitude concerning his social media activity and engagement of the media. However, his recent public comment via social media detected by AHQ media staff indicated a potential breach of Defence policy, about which he had been previously been counselled by HQ 2 Div on at least two occasions in 2015.

343. The social media activity comprised a number of comments (tweets) on a Twitter account titled Stuart McCarthy@StuartMcCarthy, which included profile photos of MAJ McCarthy in uniform. The majority of the tweets were about the former Chief of Army ( ), concerning his ( ) and some about the Prime Minister ( ). By way of example, the tweets included:

a. You should rename the award: “Most Shamefully Hypocritical” is a certainty;

b. Both and @ have made a habit of covering up criminal misconduct. This is disgraceful;

c. @BreakfastNews @alberice was directly involved in abuse and cover-up when he was. His award is a joke;

d. @ABCthedrum You’ve been duped @AttardMon. was involved in a series of cover-ups and criminal misconduct when he was;

e. Why are you and your government so determined to flush human veterans down the toilet?

f. I live in your electorate but you refuse to see me. You are a disgrace;

g. @ @MykeRetribution I live in electorate and he refuses to see me, a constituent. Happy to flush us down the toilet; and
h. @MykeRetribution It’s a safe assumption is up to his neck in corruption, the same as every other politician.

344. As a result of these tweets AHQ requested HQ 2 Div to take a firmer approach with MAJ McCarthy about his social media presence. Specifically,-directed HQ 2 Div formally counsel MAJ McCarthy, restating to him the requirement to comply with Defence social media policy, and secondly, that a discipline investigation be conducted to determine whether DFDA or other adverse action was warranted.

345. On 03 February 2016, conducted an interview with MAJ McCarthy, and a Record of Conversation was completed. The interview was in two parts, the first relating to his medical status and his request to DOCM-A of December 2015.

MAJ McCarthy was advised that no response had been received from DOCM-A. This discussion was carried out in the presence of MAJ McCarthy’s rehabilitation manager, remained to support MAJ McCarthy throughout. MAJ McCarthy did not want to participate in the interview saying he was not up to it, and requested to provide the counselling in writing. offered to hold the counselling the next day but not to do it in writing. MAJ McCarthy agreed to continue that day and said, ‘Okay, I will listen but I will not comment.’

346. began the counselling by explaining MAJ McCarthy’s ‘recent use of twitter to attack’ was against Defence policy. The policy was explained to him, ‘in particular...that it was an offence to post information that is likely to bring discredit upon the Defence Force.’ read extracts of the Defence Instruction to him and indicated how the twitter comments contravened Defence policy. The Record of Conversation between and MAJ McCarthy proceeded as follows:

MAJ McCarthy stated that the VCDF defamed him publicly on twitter when he released a press release [24 August 2015] that challenged MAJ McCarthy’s submission to the Senate Inquiry into ADF Mental Health. He asserted that the VCDF called him “a liar” when he stated that MAJ McCarthy had made “unsubstantiated claims”. I tried to explain that using respectful language such as unsubstantiated claims was significantly different to terms that he had used such as “His award is a joke” (referring to and his calling a disgrace. I do not believe he could differentiate between respectful and disrespectful language. As part of this discussion MAJ McCarthy questioned why the VCDF is able to discredit him publically, [sic] yet he is not allowed to reciprocate. I explained to MAJ McCarthy that there was a right and a wrong way to pursue his grievances.

347. At interview confirmed the events contained in the Record of Conversation and MAJ McCarthy’s focus was on the press release by VCDF, and his belief it was unfair that VCDF could defame him, but he could not respond. indicated MAJ McCarthy did not directly admit to the twitter comments, nor did directly ask him about them.
348. On 04 February 2016 advised AHQ by email the counselling of MAJ McCarthy had been conducted, and in his opinion undertaking a disciplinary investigation would be of little benefit as he did not agree with charging MAJ McCarthy under the DFDA. At interview suggested, given the nature of MAJ McCarthy’s comments and his previous formal counselling on the matter in 2015, AHQ were directing a DFDA investigation to protect themselves from any insinuation they were treating MAJ McCarthy differently to others. He stated AHQ were saying ‘anyone else that was doing what he [McCarthy] was doing in the media would be charged. What we [AHQ] want is some trail that says these are the reasons why we didn’t [charge him], even though we could of. So [AHQ] wanted that investigation to be done so they could say, look, the reason we didn’t take action in this case was for this.’

349. Following the counselling of MAJ McCarthy by his CO, initiated a discipline investigation using the local Service police. As MAJ McCarthy was absent from his unit on the Service police were unable to make contact with him to conduct a DFDA interview. Following further discussion with AHQ, and the unit legal officer, formed the view it would not be appropriate for the Service police to pursue the matter through more formal means. Instead, he decided to conduct the DFDA interview using an officer at HQ 2 Div ( ), who was a former RSM.

350. At interview, noted it had often been difficult to contact MAJ McCarthy but he had in the past responded to SMS texts. Hence, sent the SMS text on 17 February 2016 to MAJ McCarthy stating, ‘Stu, you are to present at HQ 2 Div in order to participate in an interview in relation to recent media comments made in social media. Contact to arrange a suitable date and time within the next week for that interview to occur. Acknowledge receipt of this text.’

351. MAJ McCarthy responded to stating, ‘Sir, has participated in a reprisal against me....’; and five minutes later with, ‘if was going to make allegations against me I request that he do so in writing so I can respond appropriately with legal advice.’ understood the reprisal to be connected with the counselling that took place on 03 February 2016 where spoke to MAJ McCarthy about his social media commentary and reminded him of Defence policy. believed MAJ McCarthy considered counselling was a reprisal against him because he was speaking up in relation to mefloquine. At interview explained, ‘From my point of view that is not true because what was speaking to Stu about was the most recent comments in social media ... the sorts of things that Army Headquarters took exception to were not comments about Mefloquine, but they were derogatory comments made about the Prime Minister and other prominent people. ... my opinion is that Stu’s perception of what is a reprisal or what is not a reprisal is slightly askew. The three SMS texts above were provided to the Inquiry by MAJ McCarthy as part of his complaint of harassment. A further series of SMS texts then followed over the next few days, which were read out by during his interview, and discussed.

352. did not respond to the third text seeking provide his allegations against MAJ McCarthy in writing. MAJ McCarthy sent another text later that night (17 February 2016). An excerpt of this lengthy SMS text is reproduced below as it provides background to MAJ McCarthy’s complaint and.
Sir, [...

ince reviewing your direction this morning I have made a further complaint to IGADF. I now await your further direction as to how to respond to your direction this morning.

353. On Friday 19 February 2016 [...]

MAJ McCarthy replied that day requesting a legal officer and he was provided with the contact details an ARES LTCOL legal officer. The officer contacted [....] over the weekend and it was made clear that it was a DFDA interview that was to be conducted.

354. On Monday 22 February 2016 MAJ McCarthy contacted [.....] and the SMS text conversation described by [....] proceeded as follows:

Sir, I'm attending a [.....] at Randwick at 0800 on Wednesday. I can see you any time after that, so from 0900. Based on legal advice I do not wish to participate in a record of interview. ' I then wrote back to him at 1500 that same day and said, "Stu, thanks. Report to the headquarters at 0900. We need to address a few administrative issues, including leave and support mechanisms while you await further advice. We also need to interview you in relation to recent social media posts. If you choose not to respond to the questions put to you in that interview, based on your legal advice, that is your prerogative. As I indicated previously, and a legal officer present if you wish." Stu then replied, 'Sir, wilco. I am yet to receive an acknowledgement of the SOR I submitted to DOCM more than two months ago.'"

355. MAJ McCarthy attended HQ 2 Div on 24 February 2016 without a legal or medical officer, and an interview was conducted with him by [.....] to discuss administrative issues. A Record of Conversation was made, [.....] was offered a support person, which was accepted by MAJ McCarthy and he was present throughout the interview. MAJ McCarthy was provided with a minute from DOCM-A confirming [.....] had been accepted. Then spoke to MAJ McCarthy about his obligation to advise him of any absences from the Sydney region, such as his forthcoming attendance at the public health seminar on mefloquine facilitated by the RSL being conducted in Townsville. had no objections to him attending, but HQ 2 Div also needed to ensure that
MAJ McCarthy's absence was approved. Finally, MAJ McCarthy was reminded of the Defence policy on public comment and social media and told that while the ADF was tolerating his public comment on mefloquine, derogatory comments against politicians and senior ADF officers was not acceptable.

356. Following the discussion with the CO, a separate discipline interview was conducted by and commenced by the Service Police. After being cautioned at the beginning of the interview, MAJ McCarthy indicated that based on legal advice he did not wish to answer any questions and the interview was terminated. The Discipline Investigation Report recommended no disciplinary action be taken as it was not possible to prove to the required standard that the twitter account was operated by MAJ McCarthy.

357. The subsequent HQ 2 Div Information Brief for the COFS AHQ, recommended disciplinary action not be pursued. In summary HQ 2 Div believed further disciplinary investigation and action would achieve little, and likely could lead to further complaints of reprisals by MAJ McCarthy and more public comment. Accordingly, noting MAJ McCarthy's health condition and his impending discharge, ongoing formal counselling was recommended as the best course of action for his welfare, and to monitor and control his media profile and comments so as to ensure he did not make personal attacks or inappropriate comments about individuals in the future. AHQ did not challenge the HQ 2 Div recommended approach, and to date there have been no further inappropriate social media personal attacks on individuals made by MAJ McCarthy. believes that as MAJ McCarthy has now received a posting to South East Queensland to position him with family and as MAJ McCarthy has a new doctor in that location whom he appears pleased with, the complaints and public comments will reduce.

358. In conclusion, during interview indicated that he had not seen any evidence to support MAJ McCarthy’s allegations he had been intimidated and threatened for speaking out on mefloquine. Rather, stated:

Where those higher [AHQ] have taken exception it hasn’t necessarily been on the Mefloquine issue. It’s been in relation to what I’d loosely describe as “other comments” in social media. ... I think those higher are reasonably relaxed about Stu making comments in relation to Mefloquine. Where the line is - is when Stu starts making comments that aren’t in relation to Mefloquine, e.g. the sorts of things that you’ve seen, and that’s the major concern. And again, if you’re Stu McCarthy and you’re seen in social media to be connected with comments like the ones he’s made about the PM ... and others, in many ways it does nothing other than erode your credibility. And we’ve also - we’ve tried to encourage Stu to see it that way.

Analysis and assessment of evidence

359. MAJ McCarthy’s first complaint of threatened disciplinary action arose from counselling that occurred on 26 March 2015. It is not disputed and is clearly evidenced by a Record of Conversation (ROC), that on 26 March 2015 MAJ McCarthy was advised by his CO during formal counselling ‘that failure to abide by the CO directions’, concerning his (MAJ McCarthy’s) public comment, dissemination of official information and use of social
media, ‘may result in discipline/administrative action’ being taken against him. However, in contrast to the agreed ROC, the basis of MAJ McCarthy’s complaint is his belief this ‘threatened’ disciplinary action was improper and unwarranted, because it was instigated by as a result of their email exchange and telephone conversation in early February 2015 concerning the permanent effects of mefloquine and the provision of appropriate care for personnel affected by ‘mefloquine neurotoxicity’.

360. The Inquiry accepts the unchallenged documentary evidence, that formal counselling (and the warning of possible administrative/disciplinary action) was only instigated following the discovery in mid-March 2015 of MAJ McCarthy’s posting of official information and comments about Defence members and policy on social media (Facebook). The Inquiry finds MAJ McCarthy’s Facebook postings could reasonably be judged as inappropriate, unacceptable and/or insubordinate, and likely to undermine or prejudice Defence’s reputation, thereby contravening Defence media and public comment policy (as set out in DI(G) ADMEST 8-2 Use of social media by Defence personnel and DI(G) ADMIN 08-1 Public comment and dissemination of official information by Defence personnel).

361. There is no evidence to support MAJ McCarthy’s inference the threatened disciplinary action was instigated by as a result of their disagreement over mefloquine. On the contrary, MAJ McCarthy was advised during counselling he could continue to use Facebook to pursue his interest about raising awareness about the risks associated with mefloquine, as long as he did not post information that could be considered prejudicial to his position as an officer in the ADF.

362. In conclusion, the Inquiry assesses MAJ McCarthy was not improperly threatened with disciplinary action on 26 March 2015, but was appropriately advised or warned of the potential consequences of failing to comply with Defence policy about public comment, dissemination of official information and the use of social media.

363. MAJ McCarthy’s second complaint is an allegation of intimidation by VCDF and his CO comprising a public attack on his credibility and a threat of disciplinary action, which were both orchestrated to dissuade him from giving evidence about the ADF’s use of mefloquine at a Senate Inquiry into the mental health of ADF personnel. The allegation arises out of an Australian newspaper article of 24 August 2015 quoting MAJ McCarthy from his Senate submission, and VCDF’s ‘on the record’ reply that day which included a statement that many of the claims in the article were unsubstantiated, particularly those concerning the unethical nature of the East Timor anti-malarial drug trials involving mefloquine. The oral and documentary evidence of events received by the Inquiry is generally consistent, and the complaint of intimidation is premised on inferences MAJ McCarthy had drawn from events rather than direct comments made.

364. It is not in contention that asked MAJ McCarthy whether he had been involved in writing the newspaper article, at the same time reminding him of their previous discussions about the limitations on speaking to the media on the broader mefloquine issue. Both MAJ McCarthy and agree accepted MAJ McCarthy’s explanation he had not spoken to the journalist and the references in the article quoting him were sourced from his Senate submission. It is evident that at the time of the conversation (when neither nor MAJ McCarthy were aware of the VCDF’s response), the reminder about speaking to the media was not regarded by MAJ McCarthy as an improper threat of disciplinary action by It is only when MAJ McCarthy later became aware of VCDF’s ‘on the record’ response to the
media article that he formed the view the CO's reminder not to speak to the media was a threat of disciplinary action, which had come down the chain of command as part of an orchestrated act of intimidation against him because he was about to appear before a Senate Inquiry.

365. MAJ McCarthy's belief the CO's reminder or warning was a command-directed threat of disciplinary action is not supported by evidence from AHQ or VCDF. The Inquiry accepts as credible the explanation that MAJ McCarthy and concludes there was no improper threat of disciplinary action made by the CO during that discussion. Accordingly, the Inquiry assesses MAJ McCarthy drew an inference that was not reasonably open from the available evidence.

366. The Inquiry accepts that a reasonable assessment of the 'on the record' response by VCDF would conclude there was no intended or actual intimidation of MAJ McCarthy. The VCDF response did not focus on MAJ McCarthy and did not personally attack his credibility, but sought to address and to correct claims and allegations in the newspaper article Defence considered were inaccurate and unsubstantiated, particularly those about the unethical conduct of the anti-malarial drug trials. Accordingly, MAJ McCarthy's belief the reference in the response to a number of unsubstantiated claims was 'a direct attack on [his] credibility ... by the Vice Chief of the Defence Force ... making deliberately deceitful claims about me ... to which I had zero right of reply', is not accepted by the Inquiry as a credible inference to be drawn from the evidence. In other words, while the newspaper article may have sourced its claims and allegations about the ADF's use of mefloquine from MAJ McCarthy's Senate submission, which MAJ McCarthy believed clearly proved or substantiated those claims and allegations, this does not support MAJ McCarthy's conclusion or inference drawn that any comments about those matters by Defence could reasonably be inferred as a deliberate and deceitful attack on his credibility.

367.

368. In the months following MAJ McCarthy's Senate Inquiry appearance, there is no evidence to show MAJ McCarthy was threatened with disciplinary action for publicly expressing concerns about mefloquine. Rather, to the contrary, it is evident MAJ McCarthy exercised his 'right of reply' by maintaining a high profile in mainstream media with a number of newspapers articles featuring his experiences with mefloquine and his concerns about its permanent long term effect on Defence members. The Inquiry assesses MAJ McCarthy's CO at HQ 2 Div and AHQ had given MAJ McCarthy significant latitude concerning his media engagement, tolerating comment which potentially breached Defence public comment policy, as long as he did not make personal attacks on Defence members, or inappropriate comments about Defence policy.

369. On 03 February 2016, MAJ McCarthy was counselled about the tweets in late December 2015 and January 2016 of inappropriate comments about the former Chief of Army and the Prime Minister on a Twitter account, titled Stuart McCarthy@StuartMcCarthy, which included profile photos of him in Army uniform. Major McCarthy did not deny or admit to making those comments, or that the Twitter account was his. Given the identifying information associated with the Twitter account—including a photograph of MAJ McCarthy in uniform, and the subject matter of the tweets themselves—in the absence of a denial by MAJ McCarthy as to ownership of
the account, the Inquiry is satisfied the Twitter account titled Stuart McCarthy@StuartMcCar
thy belonged to MAJ McCarthy and the December 2015 and January 2016 tweets were posted by him.

370. MAJ McCarthy’s subsequent complaint of intimidation and harassment against his CO and COFS HQ 2 Div, for seeking to conduct a further interview with him about the social media comments, was resolved when MAJ McCarthy was provided with legal advice and became aware that the purpose of directing him to attend HQ 2 Div was twofold, namely to deal with administrative matters and to conduct a DFDA (not an administrative) interview with him about his social media comments. In any event, there is no evidence to support the allegation that a direction to make an appointment for an interview with his CO to discuss recent social media comments was intimidation or harassment of MAJ McCarthy, merely because the CO had previously discussed the matter with him. Furthermore, a direction to attend HQ 2 Div for a DFDA interview, as part of a disciplinary investigation, is of itself not unlawful, as long as the DFDA rights of the member are observed in any interview that may be conducted.

371. A disciplinary investigation was conducted into MAJ McCarthy’s alleged breach of Defence public comment and social media policy for the posting of derogatory comments about the former Chief of Army and the Prime Minister. MAJ McCarthy, acting on legal advice, declined to answer questions at interview. Ultimately, a decision was made not to proceed with DFDA action against MAJ McCarthy. The Inquiry is satisfied the instigation and conduct of the disciplinary investigation was appropriate (fair and reasonable), particularly given MAJ McCarthy’s previous formal counselling on the matter. There is no evidence the disciplinary investigation was initiated as an abuse of power to harass or intimidate MAJ McCarthy for publicly commenting on the effects of mefloquine on Defence members. Rather, the investigation was conducted into MAJ McCarthy’s inappropriate and derogatory comments about senior current and former ADF officers and politicians made on public social media.

FINDING 45: Between 27 January 2015 and 03 February 2015, MAJ McCarthy and
had a telephone conversation and an email exchange resulting in a disagreement concerning the permanent effects of mefloquine and the provision of appropriate care for ADF personnel affected by ‘mefloquine neurotoxicity’.

FINDING 46: On 15 March 2015 MAJ McCarthy posted comments on Facebook about the Surgeon General ADF (SGADF) and command of an ADF medical system that was criminally negligent in relation to the use of mefloquine and veteran’s mental health, and covered up the truth about the effect of the drug. He also posted an official briefing document on mefloquine.

FINDING 47: On 17 March 2015 MAJ McCarthy advised Joint Health Command he had posted his email exchange with on his Facebook page with added explanatory comments about accusing him, amongst other things, of covering up and lying to senior officers about the effects of mefloquine, and conducting an infamous drug trial which poisoned 1100 diggers with a neurotoxicant causing them permanent brain injuries.

FINDING 48: MAJ McCarthy was identifiable from his publicly accessible Facebook account as a member of the ADF. The comments on Facebook concerning and the SGADF could reasonably be considered as inappropriate, unacceptable and/or insubordinate, and likely
to undermine or prejudice Defence’s reputation, thereby contravening Defence social media and public comment policy.

FINDING 49: The posting of official documentation, including the email exchange with [REDACTED] on Facebook contravened the Defence policy on the dissemination of official information by Defence personnel on social media.

FINDING 50: On 26 March 2015 MAJ McCarthy was formally counselled by his Commanding Officer about Defence policy on public comment, dissemination of official information and use of social media policy, and a Record of Conversation made. The formal counselling was instigated by Army Headquarters as a result of the inappropriate comments made on Facebook by MAJ McCarthy concerning [REDACTED] and the SGADF. During that counselling MAJ McCarthy was advised that failure to comply with Defence policy may result in discipline or administrative action being taken against him.

FINDING 51: There is no evidence to support MAJ McCarthy’s claim the threatened disciplinary action (made during the formal counselling on 26 March 2015) was instigated by [REDACTED] as a result of their email exchange and telephone conversation in early February 2015, and their disagreement over the provision of appropriate care for personnel affected by mefloquine neurotoxicity.

FINDING 52: MAJ McCarthy was not threatened with disciplinary action on 26 March 2015 for publicly expressing concern for individuals allegedly affected by mefloquine; rather he was informed he could continue to use Facebook to pursue his interest about raising awareness about the risks associated with mefloquine, as long as he did not post information that could be considered prejudicial to his position as an officer in the ADF.

FINDING 53: On 24 August 2015, MAJ McCarthy was asked by his CO whether he had been involved in writing an Australian newspaper article (published that day) about the conduct of unethical anti-malarial drug trials by the ADF. At the same time MAJ McCarthy was reminded by his CO of their previous discussions about speaking to the media on the broader mefloquine issue. The CO accepted MAJ McCarthy’s explanation he had not spoken to the media and the newspaper article was quoting from his written submission in July 2015 to the Senate Inquiry into the mental health of ADF personnel.

FINDING 54: The Vice Chief of the Defence Force (VCDF) ‘on the record’ response of 24 August 2015 did not focus on MAJ McCarthy and did not personally attack his credibility, but sought to address and to correct claims and allegations in the Australian newspaper article Defence considered were inaccurate and unsubstantiated, particularly those about the unethical conduct of the anti-malarial drug trials. The ‘on the record’ response was not intended to intimidate MAJ McCarthy in order to dissuade him from giving evidence before the Senate Inquiry into the mental health of ADF personnel. MAJ McCarthy was not dissuaded from appearing before the Senate Inquiry and giving his evidence.

FINDING 55: MAJ McCarthy’s belief the VCDF ‘on the record’ response was a direct attack on his credibility is not a credible and reasonable inference to be drawn from the evidence.
FINDING 56: The CO’s reminder on 24 August 2015 about speaking to the media was initially not regarded by MAJ McCarthy as an improper threat of disciplinary action. When MAJ McCarthy later became aware of VCDF’s ‘on the record’ response to the Australian newspaper article, he formed the view the CO’s reminder was a command directed threat of disciplinary action and part of an orchestrated act of intimidation against him because he was about to appear before a Senate Inquiry to give evidence about the ADF’s use of mefloquine.

FINDING 57: The CO was acting of his own volition, and not at the direction of command, in raising the writing of the newspaper article with MAJ McCarthy on 24 August 2015. The reminder to MAJ McCarthy about the limitations on speaking to the media about mefloquine was not an improper threat of disciplinary action.

FINDING 58: MAJ McCarthy’s allegation of intimidation by VCDF and his CO, comprising a public attack on his credibility and a threat of disciplinary action, orchestrated to dissuade him from giving evidence about the use of mefloquine in the ADF at the Senate Inquiry into the mental health of ADF personnel, is not substantiated.

FINDING 59: In the period from September 2015 to February 2016 there is no evidence MAJ McCarthy was threatened with disciplinary action for publicly expressing concerns about mefloquine. Rather, it is evident MAJ McCarthy was allowed to maintain a high profile in mainstream media with a number of newspapers articles featuring his experiences with mefloquine and his concerns about its permanent long term effect on Defence members.

FINDING 60: On 03 February 2016, MAJ McCarthy was counselled by his CO about the posting (tweeting) in late December 2015 and January 2016 of inappropriate comments about the former Chief of Army and the Prime Minister on a twitter account, titled Stuart McCarthy@StuartMcCarthy, which included profile photos of MAJ McCarthy in Army uniform. Major McCarthy did not deny or admit to making those comments, or that the twitter account belonged to him. Given the identifying information associated with the Twitter account and in the absence of a denial by MAJ McCarthy as to ownership of the account, the Inquiry is satisfied the twitter account belonged to MAJ McCarthy, and he posted the inappropriate tweets in late December 2015 and January 2016.

FINDING 61: MAJ McCarthy’s subsequent complaint of intimidation and harassment against his CO and Chief of Staff of HQ 2 Div for seeking to conduct a further interview with him about those social media comments was resolved when MAJ McCarthy was provided with legal advice and became aware that the purpose of the direction was to deal with further administrative matters and to conduct a Defence Force Discipline Act (DFDA) investigation (not an administrative) interview with him about his social media comments. The direction to arrange an appointment with his CO for an interview was legitimate and was not intimidation or harassment because the CO had previously discussed the matter with him.

FINDING 62: A disciplinary investigation under the DFDA was conducted into MAJ McCarthy’s alleged breach of Defence public comment and social media policy for the posting of derogatory comments about the former Chief of Army and the Prime Minister (and others). Following legal advice, MAJ McCarthy declined to answer questions at interview, and ultimately DFDA action was not proceeded with. The instigation of the disciplinary investigation
was appropriate (fair and reasonable), particularly given MAJ McCarthy's previous formal
counselling on the matter.

FINDING 63: The conduct of the DFDA investigation was not an abuse of power to harass or
intimidate MAJ McCarthy for publicly commenting on the effects of mefloquine on Defence
members, but was initiated as a result of inappropriate comments about individuals on public
social media.

FINDING 64: MAJ McCarthy was not threatened with disciplinary (or administrative) action for
publicly expressing concern for individuals allegedly affected by mefloquine. On four occasions
(26 March 2015, 24 August 2015, 03 February 2016 and 24 February 2016) MAJ McCarthy was
counselling or reminded of the Defence policy about making public comment as an identifiable
Defence member in the media and on social media. The formal counselling sessions with his CO
(and the disciplinary investigation) were properly initiated as a result of inappropriate and
derogatory comments made by MAJ McCarthy about senior ADF officers and politicians on
social media, and not as a result of his public comment and discussion about mefloquine.
Defence accepted that MAJ McCarthy would continue to make public comments, which were in
potential breach of media policy, and chose to deal with those comments by responding publicly
to address any matters he raised.

DIRECTION 4:

Determine whether COL Brennan became aware of any adverse affects of mefloquine
neurotoxicity on Defence personnel. If yes, did he follow relevant health protocols and notify
his chain of command.

372. MAJ McCarthy complains in his submission and at interview that COL Brennan has failed
on at least three occasions to disclose what MAJ McCarthy alleges were the known permanent
neurotoxic adverse effects of mefloquine to appropriate authorities, or in published research papers.
MAJ McCarthy believes these actions are tantamount to fraud (deceptive or misleading conduct) or
negligence, by COL. Brennan.

First complaint

373. MAJ McCarthy's first and principal complaint concerns the failure of the published study
paper on the 2000-2001 tafenoquine versus mefloquine trial in East Timor to include known
evidence that 'mefloquine had been found to be neurotoxic, able to cause lasting or permanent
brain injury with long term or permanent neuropsychiatric side effects to trial subjects.' As
COL Brennan was the co-author of the study paper and now a senior officer, MAJ McCarthy
believes he should be held responsible for this allegedly fraudulent document.

374. The study paper on the AMI tafenoquine/mefloquine trial conducted in 2000-2001 was not
published until February 2010. The paper was primarily authored by the Principal Investigator in
the trial, In his submission to IGADF, MAJ McCarthy states in 2006 there
was a published study paper or report concerning mefloquine neurotoxicity, which should have
been referred to in the 2010 AMI study paper, and the failure to do so was fraudulent.
MAJ McCarthy subsequently indicated in his October 2015 research paper on the ethics of the AMI
mefloquine trials in Timor Leste (which he provided to the Inquiry), that the 2006 study referred to
in his submission was carried out on animals (rats). MAJ McCarthy’s October 2015 research paper provides no analysis linking the 2006 animal study to his claim in his submission that ‘mefloquine had been found to be neurotoxic, able to cause lasting or permanent brain injury with long term or permanent neuropsychiatric side effects to trial subjects .... ’ (that is, to humans).

375. BRIG Brennan was interviewed on 06 May 2016 and questioned about MAJ McCarthy’s complaint and the allegation of fraud made against him. He denied there was any fraud or deceptive conduct by him or the authors of the study paper. He indicated it was not appropriate or necessary to refer to subsequent scientific findings on mefloquine neurotoxicity in the context of a trial which was testing tafenoquine. Specifically, BRIG Brennan stated that:

[T]his [the tafenoquine trial] was a study into the safety and tolerability of Tafenoquine. Mefloquine was a comparator so that the perspective is 100 per cent around Tafenoquine. There [are] no comments mentioned in any of the documentation to look into Mefloquine. So when you publish a paper talking about Tafenoquine [to] then raise issues about the comparator drug and its safety and tolerability outside the context of comparing it to [Tafenoquine]- it’s inappropriate.

He went on to note researchers would probably reference studies concerning tafenoquine that had been completed since their study including subsequent findings; however, they would only refer to the side effects of mefloquine in the context of comparing it to tafenoquine.

376. BRIG Brennan added that the peer review process of a study paper will assist in detecting any flaws in the research and may require additional information to be provided (which was not the case concerning the matters raised by MAJ McCarthy in his submission and papers). He commented, ‘As a general rule, when you’re publishing your research you’re publishing your research as distinct from being a literature search for everyone else’s research.’

377. At interview the Principal Investigator in the 2000 to 2001 tafenoquine trial, was also asked to comment on MAJ McCarthy’s allegation about the failure to include later studies on mefloquine in the 2010 published study paper, of which he was the principal author. He noted the study paper was about the findings of the trial (into tafenoquine) and matters that are not of interest to that trial (such as those raised by MAJ McCarthy) are not included. He said, ‘ ... you pick out the key elements that are going to inform your reading population about your experiences in conducting that trial... ’ He rejected the allegation the study paper (on tafenoquine) was selective in failing to include later studies or research on mefloquine.

378. On 30 September 2015 MAJ McCarthy made a similar allegation of fraud (as one of five complaints) to ADHREC about the conduct of the AMI drug trials. The complaint was headed, ‘(5) Fraud. [and went on to state] When the trials reports were eventually published relevant scientific findings regarding mefloquine CNS toxicity were omitted’. The complaint contained no further detail as to why MAJ McCarthy considered the alleged omissions were fraudulent. The response from ADHREC was provided on 29 October 2015. It was unclear to them whether MAJ McCarthy was referring to not only the tafenoquine trial research paper published in 2010, but also to the mefloquine/doxycycline trial study paper which was published in 2005 (before the 2006 study on animals). In any event, in its response to MAJ McCarthy, ADHREC said it was a matter for the researchers to put the information they thought was relevant in their paper to permit scrutiny of their findings from the trial and to contribute to public knowledge in accordance with the
National Statement (NHMRC) guidelines. They added that the interpretation of the findings was then open to academic debate. The ADHREC review of MAJ McCarthy’s complaint concluded from the documentation available at the time of the trial(s) (which were approved by ADHREC and conducted by AMI), that there was nothing to indicate Defence and ADHREC did not apply rigorous scientific and ethical evaluation to the trial, including in the published research findings.

Second complaint

379. MAJ McCarthy’s second complaint of fraudulent behaviour (or negligence) was raised at interview and is discussed briefly in the research paper MAJ McCarthy wrote on the ethics of the 2000 to 2002 AMI mefloquine trials in East Timor. The substance of the allegation is that then-LTCOL Brennan and the other investigators in both the mefloquine and tafenoquine trials were either fraudulent or negligent in not being aware of studies done prior to the AMI trials which suggested permanent adverse neurotoxic effects of mefloquine were foreseeable; and this information should have been included in the consent forms and medical briefings to trial participants and provided to ADHREC. MAJ McCarthy’s research paper on the ethics of the 2000 to 2001 AMI mefloquine trials in Timor Leste provides no analysis on how he reached his conclusion that mefloquine neurotoxicity was evident or foreseeable from the findings of those earlier studies.

380. The content of the medical briefings and the consent forms concerning the side effects of mefloquine is discussed in Direction 2 dealing with the issue of informed consent. In short, there was no information in the consent form in either trial concerning mefloquine neurotoxicity as a potential side effect of mefloquine use. This was consistent with the 1998 Lariam (mefloquine) Product Information and Consumer Medicine Information. These TGA approved documents did not recognise the alleged permanent neurological side effects of mefloquine (mefloquine neurotoxicity), claimed by MAJ McCarthy to have been known or at least foreseeable at the time from earlier studies.

381. As discussed in Direction 2 and in the third complaint below, BRIG Brennan has given evidence that permanent neurological side effects of mefloquine were not known and scientifically verified in 2001, and permanent injury to the brain and the central nervous system (mefloquine neurotoxicity) raised by MAJ McCarthy is still not accepted by scientific study. BRIG Brennan also made it clear he ‘was unaware that anything in the study revealed any new or unexpected side effects [of mefloquine]’ and, therefore, he did not fail to pass on such matters to his chain of command.

Third complaint

382. The third allegation is that COL (now BRIG) Brennan has covered up and misled (and continues to mislead), VCDF and senior officers in the ADF about the true impact of mefloquine neurotoxicity on ADF personnel. In his submission MAJ McCarthy states: ‘based on [Ministerial] correspondence and media statements from VCDF [which he asserts at interview is written by, or on advice from COL Brennan], there is strong evidence that COL Brennan is attempting to cover up the true impact of mefloquine neurotoxicity on ADF personnel.’ At interview he added the information provided in various correspondence ‘is simply false and misleading [and] inconsistent with the manufacturer’s information and scientific literature.’ MAJ McCarthy also made a similar accusation publicly in his Facebook page (as discussed in Direction 3), which
accuses then-COL Brennan of misrepresenting recent research on the effects of mefloquine to senior ADF leaders.

383. In support of this complaint, MAJ McCarthy makes reference to an example of misleading ministerial correspondence in his second supplementary submission to the Senate Inquiry in September 2015. A letter of 24 May 2015 from the Assistant Minister for Defence to Senator Whish-Wilson states: ‘... significant side effects [of mefloquine] are uncommon...’ This correspondence was not provided to the Inquiry nor was the context of the quotation indicated. In any event, MAJ McCarthy claims this statement is inconsistent with the 2014 Product information on Lariam (mefloquine), which states anxiety and depression (amongst other things) are 'common' side effects of mefloquine. He claims it must follow that anxiety and depression are 'significant' side effects, and therefore, the Assistant Minister's letter makes a false claim. MAJ McCarthy concludes that VCDF, as the adviser on such matters, has misled the Assistant Minister. MAJ McCarthy goes on to suggest that as VCDF receives his advice from JHC, in particular COL Brennan, then this is evidence of COL Brennan attempting to cover-up the true side effects of mefloquine.

384. As discussed in Direction 2, the Product Information contains the scientific and technical information about the drug. Terminology such as 'common' or 'uncommon' have specific statistical meanings when used to describe the adverse effects of a drug. The 2014 Lariam Product Information details post marketing data (not scientific studies) on the use of Lariam, which reveal that anxiety and depression are reported as 'common'. However, the 2014 Lariam Consumer Medicine Information (CMI), which is the information provided to the individual about the drug and explained by the doctor, uses similar terminology, but not in a statistical sense rather within its ordinary meaning. The CMI lists two types of potential side effects, the first described as the 'more common or general mild' side effects; and the second group, as 'serious side effects' which are 'rare'. Anxiety and depression are listed as serious but rare side effects.

385. The second type of misleading correspondence referred to by MAJ McCarthy is misleading VCDF media statements, which he suggests are drafted from advice provided by COL Brennan. In his Senate submission, the only reference to a media statement is the VCDF's 'on-the-record' response of 24 August 2015, which is discussed earlier in Direction 3. In short, MAJ McCarthy believes the statement by VCDF (drafted on advice from COL Brennan), that many of the claims in the Australian newspaper article are unsubstantiated, is a direct attack on his credibility, and seeks to undermine the validity of his analysis of the side effects of mefloquine contained in his Senate submission and supporting papers. By attacking his credibility and denying mefloquine causes permanent brain or CNS injury (mefloquine neurotoxicity), MAJ McCarthy is inferring that COL Brennan is seeking to cover up and mislead VCDF and the wider ADF community on the true effects of mefloquine.

386. At interview BRIG Brennan denied he has misled the chain of command about the side effects of mefloquine. Although, he did not recall the specific Ministerial letter referred to by MAJ McCarthy, he was involved in providing information and advice to VCDF, such as for the VCDF 'on-the-record' response of 24 August 2015 to The Australian newspaper article. BRIG Brennan indicated that in JHC briefings provided to VCDF and senior ADF officers, it is noted that mefloquine like all medications has known side effects, which generally resolve soon after ceasing the medication. However, in rare cases the side effects may be long lasting or permanent. BRIG Brennan accepts that a ‘... real development is that some of those side effects may
now become - the neurological ones - might be permanent rarely.' These include 'balance and hearing, tinnitus.' However, there is no scientific evidence of permanent brain injury caused by mefloquine (mefloquine neurotoxicity) and '... we've also said consistently that it doesn't cause or trigger PTSD.'

387. The Mefloquine and the Frequently Asked Questions (FAQ) sections of the publicly accessible Department of Defence, Defence Health website, 'Malaria, mefloquine and the ADF' provides information about mefloquine and the ADF's use of the drug. Detail is provided on the common and uncommon side effects of mefloquine consistent with approved TGA information. It is acknowledged that in rare cases the side effects may persist for months or longer and in some people, the side effect may be permanent. However, mefloquine neurotoxicity is not recognised or referred to in the website. The information in the JHC website is provided by BRIG Brennan and his staff. Information provided by JHC in Defence media releases about the side effects of mefloquine is consistent with the website.

Analysis and assessment of evidence

388. MAJ McCarthy's first complaint is that the 2010 study paper concerning the 2001 tafenoquine/mefloquine trial was fraudulent in not including the findings of a subsequent 2006 study on mefloquine neurotoxicity in animals. MAJ McCarthy did not provide any analysis as to how this later study supported his claim that 'mefloquine had been found to be neurotoxic, able to cause lasting or permanent brain injury with long term or permanent neuropsychiatric side effects to trial subjects' (humans).

389. Regardless of the validity of MAJ McCarthy's claims about the 2006 study paper proving mefloquine neurotoxicity in human subjects, both BRIG Brennan and ADHREC provide reasonable explanations as to why there was no requirement to include reference to this later study in the 2010 AMI study paper for the tafenoquine trial. The AMI study was trialling the safety, tolerability and effectiveness of a new unregistered drug, tafenoquine. Mefloquine was used in smaller numbers as a control or comparator. It logically follows that the subsequent study in 2006 concerning mefloquine neurotoxicity (regardless of its validity) is not relevant to, and does not affect, the 2001 trial findings about tafenoquine. Noting it is a matter for the researchers to decide what information to include in a study paper, the Inquiry is satisfied that a decision not to include information on mefloquine neurotoxicity in a trial of tafenoquine was reasonably open to the authors of the study paper.

390. MAJ McCarthy's second complaint is that COL Brennan and other investigators in the 2000 to 2002 AMI mefloquine trials in East Timor failed to include information in the trial briefings and documentation provided to ADHREC and trial participants gained from earlier studies, which he claims showed the neurotoxic side effects of mefloquine were foreseeable. This allegation is premised on MAJ McCarthy's assertion in his research paper (with no analysis), that these earlier studies provide sufficient information to foresee the issue of mefloquine neurotoxicity at the time of the East Timor trials. The Inquiry directions do not include a requirement to analyse the scientific evidence concerning the side effects of mefloquine and, for this and other reasons, MAJ McCarthy's assertion has not been able to be verified by the Inquiry. However, the evidence on the informed consent process (discussed in Direction 2) indicates the AMI trial documentation provided to ADHREC and to trial participants concerning the side effects of mefloquine was consistent with the TGA approved 1998 Lariam (mefloquine) Consumer Medical Information and
Product Information. Both those documents do not recognise and list mefloquine neurotoxicity as a potential side effect of mefloquine use.

391. Accordingly, the Inquiry assesses that a claim of negligence against then-LTCOL Brennan and the other AMI investigators for failing to include alleged foreseeable information about likely mefloquine neurotoxicity side effects, which was not contained in the approved product information at the time, is not sustainable. Furthermore, there is no evidence to support an inference the failure to include this information was fraudulent, that is, deliberately deceptive or misleading.

392. The third and more general complaint that COL (now BRIG) Brennan has covered up and misled, and continues to cover up and mislead, VCDF and senior officers in the ADF about the true impact of mefloquine neurotoxicity on ADF personnel, is based on inference rather than any direct evidence. The example provided by MAJ McCarthy concerning Defence’s alleged misleading statements on the effects of mefloquine in Ministerial correspondence is clearly explained when the 2014 CMI is examined. The difficulty is there appears to be a difference in meaning to terms used in the product information such as ‘uncommon’ and ‘rare’, which are associated with quantitative measures, and similar terms used in a qualitative manner in the CMI. In apparent contradiction to the 2014 Lariam product information, the 2014 Lariam CMI (given to patients) states that anxiety and depression are serious side effects, but considered ‘rare’. Hence, the statement in the Ministerial correspondence that ‘significant side effects [of mefloquine] are uncommon’, when referring to anxiety and depression, is not inconsistent with the 2014 CMI description that they are serious but rare side effects; and negates any claim of deceptive or misleading conduct by COL Brennan or Defence in that correspondence.

393. There is no substantive evidence that the side effects of mefloquine as detailed in the Defence Health public website or other VCDF media releases are deceptive or misleading. While there may be a difference in meaning of the terminology used to describe the side effects of mefloquine, any inference that this is evidence of deception or a cover-up of the true side effects is not substantiated.

394. MAJ McCarthy has drawn an inference from COL Brennan’s failure to accept that mefloquine use causes permanent brain or CNS injury (mefloquine neurotoxicity), which MAJ McCarthy believes is scientifically accepted, is an attempt to cover up and mislead VCDF and the wider ADF community on the true effects of mefloquine. He asserts the purpose of this cover-up is to protect the reputation of Defence and COL Brennan, and to avoid allegations not only of unethical drug trials, but also of failing to properly care for Defence members who have suffered serious adverse effects from participation in those trials. The inquiry does not accept that MAJ McCarthy’s inference concerning COL Brennan’s actions can logically or reasonably be drawn from the evidence. The non-acceptance by COL Brennan of MAJ McCarthy’s opinion about mefloquine neurotoxicity, and the decision to only provide information about the side effects of mefloquine consistent with scientific peer reviewed research and TGA-accepted product information, are not of themselves evidence of a cover up or deceptive or misleading conduct, by COL Brennan, as inferred by MAJ McCarthy.

395. In summary, the Inquiry assesses that during the conduct of 2000 to 2002 AMI anti-malarial drug trials, and subsequently, COL Brennan did not become aware of, nor fail to disclose, to appropriate authorities or his chain of command, any neurotoxic adverse side effects of mefloquine. Furthermore, COL Brennan has not engaged in any deceptive or misleading conduct in
order to cover up or hide the true impact of known neurotoxic side effects of mefloquine from senior ADF officers or the wider ADF and veteran community.

Additional complaint of conflict of interest

396. At interview MAJ McCarthy raised an additional complaint against COL Brennan. During the tafenoquine trial involving 1 RAR, then-LTCOL Brennan assisted as an investigator in the preliminary stages of the trial conducted in Townsville during the period August to October 2000. At the time LTCOL Brennan was posted as the Senior Medical Officer (SMO) at HQ 3 Bde. MAJ McCarthy alleges LTCOL Brennan’s assistance to the drug trial when he was SMO for 3 Bde involved a conflict of interest.

397. When asked to explain why there was a conflict of interest, MAJ McCarthy stated that as SMO HQ 3 Bde, LTCOL Brennan was responsible for providing medical advice to the Brigade on the conduct of the drug trial. However, as he was assisting the trial as an investigator he was not in a position to give impartial advice to the Brigade Commander (COMD 3 Bde) and CO 1 RAR about participation in the trial.

398. At interview BRIG Brennan denied there was a conflict of interest in his role as SMO for 3 Bde and his assisting in the conduct of the preliminary stages of the AMI tafenoquine trial. He indicated he was involved for about two weeks in clinical aspects of the trial interviewing and briefing participants and obtaining their consent. BRIG Brennan asserted there may have been a potential conflict of interest had he not informed COMD 3 Bde that he was assisting in the trial as an investigator. Indeed, BRIG Brennan believed that it gave COMD 3 Bde confidence knowing he supported, and was participating in, the trial as an investigator.

399. BRIG Brennan did not recall specifically briefing COMD 3 Bde on the trial but said that ... (the Principal Investigator from AMI) and he would have done so. BRIG Brennan stated the Brigade was not the ‘trial subject’. By this he meant it was a clinical trial requiring consent of individual participants and not the brigade or unit, but in order for the trial to proceed it was necessary to have CO 1 RAR’s support, and he recalled that (and not he) engaged with the CO. It was not necessary to get the permission of COMD 3 Bde to conduct the trial; the decision to support the trial or not was left with CO 1 RAR. (This is discussed in Directions 1 and 2).

400. In any event, BRIG Brennan stated that he was principally the medical adviser to COMD 3 Bde, and if CO 1 RAR wanted other medical advice on the trial, he could call on his own 1 RAR regimental medical officer (RMO) for that advice.

401. ... the Principal Investigator for the AMI trial, did not believe that there was a conflict of interest for LTCOL Brennan acting as an investigator in trial, when he was the SMO for 3 Bde. He confirmed that approval from COMD 3 Bde was not required for the conduct of the trial and it was matter for ... to speak with CO 1 RAR to gain his support for the trial. LTCOL Brennan did not provide advice on the trial to CO 1 RAR. That was a matter for ... as the AMI Principal Investigator. If the CO wanted further medical advice he could speak with his own RMO.
Analysis and assessment of evidence

402. On the evidence presented the Inquiry assesses there was no conflict of interest in then-LTCOL Brennan’s assisting as an investigator in the anti-malarial drug trial involving 1 RAR, when he was posted as the SMO at HQ 3 Bde. LTCOL Brennan advised COMD 3 Bde up front that he supported the trial and was going to assist AMI as an investigator. The trial was initiated, developed and conducted by AMI. LTCOL Brennan did not have any undisclosed interest in the trial, and his assistance to the trial would not affect the impartiality of any advice he may be called upon to provide to COMD 3 Bde.

403. As discussed in Direction 1, the 1 RAR tafenoquine trial had already been approved by Defence (ADMEC) and required the individual consent of participants and not that of COMD 3 Bde. From a practical perspective it needed the approval and support of CO 1 RAR to allow his unit members to be approached by AMI to participate in the trial. LTCOL Brennan supported the trial and was assisting as an investigator did not automatically create a conflict of interest situation should CO 1 RAR seek his advice. However, COL Brennan’s principal role was medical adviser to COMD 3 Bde and not CO 1 RAR. If the CO wanted additional medical advice from an officer not directly involved with the trial, he could call on his own 1 RAR medical officer for advice.

FINDING 65: The complaint that the 2010 published study paper on the 2000 to 2001 tafenoquine versus mefloquine drug trial in East Timor, co-authored by COL Brennan, failed to include evidence from a subsequent 2006 animal study that mefloquine had allegedly been found to be neurotoxic, able to cause lasting or permanent brain injury with long term or permanent neuropsychiatric side effects to trial subjects, is not substantiated.

FINDING 66: The purpose of the 2000 to 2001 drug trial was to assess the safety, tolerability and effectiveness of a new unregistered drug, tafenoquine. Mefloquine was used in smaller numbers as a control or comparator. It logically follows that a subsequent study in 2006 concerning mefloquine neurotoxicity (regardless of its validity) is not relevant to, and does not impact on, the 2001 trial findings about tafenoquine. The decision not to include information on mefloquine studies in a trial of tafenoquine was reasonably open to the authors of the study paper.

FINDING 67: There was no information in the consent form in either trial concerning mefloquine neurotoxicity as a potential side effect of mefloquine use. This was consistent with the 1998 Lariam (mefloquine) Product Information and Consumer Medicine Information. These TGA approved documents did not recognise the alleged permanent neurological side effects of mefloquine (mefloquine neurotoxicity), claimed by MAJ McCarthy to have been known or at least foreseeable at the time from earlier studies.

FINDING 68: A claim of fraud (deceptive conduct) or negligence against COL Brennan and the other AMI investigators for failing to include information from earlier research and studies, which allegedly showed the foreseeability of mefloquine neurotoxicity, in the medical briefings and documentation provided to both the tafenoquine and mefloquine trial participants and to ADHREC, is rejected.
FINDING 69: There is no substantive evidence that the side effects of mefloquine as detailed in Ministerial correspondence, VCDF media releases, the Defence Health public website or other documentation, using information provided by COL Brennan is deceptive or misleading. While there may be differences in terminology used to describe the side effects of mefloquine, any inference that this is evidence of deception or a cover up of the alleged true effects of mefloquine by COL Brennan is not substantiated.

FINDING 70: The non-acceptance by COL Brennan of MAJ McCarthy’s opinion about mefloquine neurotoxicity, and the decision to only provide information about the side effects of mefloquine consistent with scientific peer reviewed research and TGA-accepted product information are not of themselves evidence of a cover up or deceptive or misleading conduct, by COL Brennan, as inferred by MAJ McCarthy.

FINDING 71: During the conduct of the 2000 to 2002 AMI anti-malarial drug trials, COL Brennan did not become aware of, nor fail to disclose, any neurotoxic adverse side effects of mefloquine to appropriate authorities or his chain of command. Subsequently, COL Brennan has not engaged in deceptive or misleading conduct to cover-up or hide the true impact of alleged known neurotoxic side effects of mefloquine use (mefloquine neurotoxicity) from senior ADF officers, or the wider ADF and veteran community; and has not deliberately or negligently failed to appropriately disclose evidence of mefloquine neurotoxicity in published research study papers.

FINDING 72: There was no conflict of interest in LTCOL Brennan participating as an investigator in the AMI tafenoquine trial in 2000, involving 1 RAR, when at the same time he held the appointment as the Senior Medical Officer for the 3rd Brigade, responsible for providing medical advice to Commander 3rd Brigade.

SUMMARY AND CONCLUSION

BACKGROUND

404. MAJ McCarthy suffers from a serious health condition which he believes arises from a cause alleged to be mefloquine, which he was prescribed by Defence in 2001, while on a United Nation deployment to Ethiopia and Eritrea. MAJ McCarthy uses the term ‘mefloquine neurotoxicity’ to describe injury, allegedly caused by mefloquine.

405. Complaint. MAJ McCarthy’s complaint is wide-ranging and concerns alleged unethical and unlawful use by Defence of the anti-malarial drug mefloquine. His principal complaint is that Defence leadership, including JHC, fails to recognise that mefloquine causes permanent brain or CNS injury (mefloquine neurotoxicity); and refuses to reach out to all Defence members and veterans who were prescribed mefloquine and may now be suffering from mefloquine neurotoxicity. He also alleges that Defence leadership and now-BRIG Brennan are covering up and downplaying the extent of the effects of mefloquine on Defence members.
Scope of Inquiry: military justice

406. The Inquiry was limited by IGADF's jurisdiction to examining the military justice matters identified in MAJ McCarthy’s complaint, principally relating to clinical trials of anti-malarial drugs (mefloquine and tafenoquine) conducted by the Army Malarial Institute (AMI), involving Defence members deploying to East Timor during the period 2000 to 2002. MAJ McCarthy claims the trials were ‘unethical’ because Defence failed to comply with the National Health and Medical Research Council (NHMRC) National Guidelines for their conduct. The alleged breaches of the National Guidelines include the necessity of conducting the trials (when the risk to participants is weighed against any beneficial outcome), and the lack of medical support provided to participants. However, the main focus of MAJ McCarthy’s complaint is on the compulsion of Defence members to take part in one of the trials as a condition of deployment, and the lack of informed consent by participants in both trials. MAJ McCarthy did not take part in the East Timor anti-malarial trials.

407. The Inquiry did not examine the general use of mefloquine or tafenoquine by Defence members, or the side effects that may be caused by the use of those drugs, as these issues fall outside IGADF’s military justice jurisdiction.

CONDUCT OF ANTI-MALARIAL TRIALS (DIRECTION 1)

First trial: tafenoquine

408. The high incidence of malaria during the 1999 INTERFET deployment to East Timor provided the stimulus and need to examine new medications for protection against malaria for periods of six months duration. The first AMI clinical anti-malarial trial was a randomised, double-blind, comparative study involving 1 RAR Battalion Group, commencing in October 2000. The purpose of the trial was to evaluate the safety, tolerability and effectiveness of a new and unregistered drug, tafenoquine, using the approved and registered drug mefloquine as a comparator. Seventy-five per cent of trial participants took tafenoquine (492) and 25 per cent took mefloquine (162). As a preventative malarial dmg, tafenoquine had the advantage of a weekly dose with a long half life, which could improve compliance and protection, and be logistically easier to administer, when compared to the daily doxycycline.

409. The Inquiry found that the use of mefloquine, the ADF's second line anti-malarial drug, as a control was necessary and reasonable to scientifically evaluate tafenoquine to the evidentiary level required to support its future use and registration as an anti-malarial drug.

410. Necessity for tafenoquine trial. Tafenoquine was found to be safe, well tolerated and effective both in preventing malaria in the high risk malaria area in East Timor, and in the eradication phase upon return to Australia. Tafenoquine is not banned drug, but is yet to be registered with the Therapeutic Goods Administration (TGA). The Inquiry concludes that this is not of itself a valid basis to claim the trial was unnecessary, or failed to provide any benefit to soldiers and advancements in the treatment of malaria, as there is clear evidence to the contrary.
Second trial: mefloquine

411. Following the 1999 INTERFET experience with malaria in East Timor, there was also a need to evaluate Defence’s existing anti-malarial options against the daily doxycycline medication (the ADF’s first line anti-malarial drug). Accordingly, the second trial involved comparing the side effects and effectiveness of mefloquine with doxycycline under typical field conditions over a six-month period. The preference by command for a weekly-taken drug, the advantages in compliance, the lack of any significant long term studies of mefloquine in an operational field setting, and the need to test whether known neuropsychiatric (as opposed to neurotoxic) side effects would impact on the operational effectiveness of Australian soldiers during a six month period, together amounted to a reasonable justification for the conduct of the trial of mefloquine, an already approved and registered anti-malarial drug.

412. The second trial involved 4 RAR Battalion Group, who deployed to East Timor in April 2001, and 2 RAR Battalion Group, who deployed in October 2001. The trial involved 1157 participants from both battalion groups taking mefloquine. All the remaining approximately 1000 soldiers were still prescribed an anti-malarial, normally doxycycline, unless they were intolerant to that drug, in which case they were prescribed mefloquine.

413. **Necessity for mefloquine trial.** The trial found mefloquine was effective in preventing malaria and was safe and generally well tolerated; and concluded mefloquine should continue to be used for those who cannot tolerate doxycycline. ‘The claim there was no beneficial outcome from the trial because there was no change in Defence policy, with mefloquine remaining the second line anti-malarial, is rejected by the Inquiry. A study of sufficient numbers under field conditions for a six-month period was required to make an informed decision on the future use of mefloquine. Furthermore, the trial was appropriately conducted taking into account the TGA approved product information concerning the very low potential risks involved.

Medical support to trials

414. MAJ McCarthy’s claim that there was a lack of medical support provided to trial participants, who allegedly suffered serious adverse effects from taking the anti-malarial drugs, is not substantiated. The Inquiry finds the medical support provided to the participants before, during and following the two trials was appropriate. There is no evidence any medical issue at the time was not followed up with appropriate and proper medical care. MAJ McCarthy’s complaint is focused on the lack of medical care for ADF personnel and veterans many years after the trials concluded for alleged permanent neurotoxic side effects of mefloquine (mefloquine neurotoxicity), which is not accepted by Defence and is not the subject of the Inquiry.

415. **Individual case.** The Inquiry became aware of an individual case in which a soldier who participated in the second trial was prescribed mefloquine in circumstances in which he should not have been. This was because his medical history included a previous health condition which was inconsistent with the prescription of mefloquine. At the time of the trials, the AMI investigators did not have access to participants’ medical files and it was accepted practice to rely on participants’ own self-reporting and answers to questions about their medical history. The soldier did not disclose the previous condition to the AMI investigator as part of the informed consent process. For this reason, the Inquiry has recommended that JHC consider a mechanism to ascertain whether...
other trial participants who took mefloquine may also have had a history of a health condition which would have been a contraindication to mefloquine use.

416. **Access to medical files.** With the commencement of the *Defence eHealth System*, Defence members’ medical files are now available electronically and include warnings and alerts about important aspects of a member’s medical history. In light of this, the Inquiry recommends that in future medical trials involving Defence members, investigators be given access to participants’ electronic medical files to reduce the risk of undisclosed medical conditions which may affect participation in the trial.

**Approval to conduct trials**

417. The protocols for the conduct of both anti-malarial drug trials were approved in accordance with the NHMRC National Guidelines by the then Australian Defence Medical Ethics Committee (ADMEC), now the Australian Defence Human Research Ethics Committee (ADHREC), a committee of impartial experts responsible for ensuring such trials are both ethically permissible and scientifically correct. Furthermore, the Inquiry finds that the trials were conducted ethically and lawfully by the AMI, in accordance with the National Guidelines issued by the NHMRC and the TGA. In the circumstances at the time, the use of the anti-malarial drugs tafenoquine and mefloquine was justified, reasonable and consistent with relevant health policy and guidance.

**INFORMED CONSENT: POTENTIAL DRUG SIDE EFFECTS (DIRECTION 2)**

418. The focus on MAJ McCarthy’s complaint about the alleged unethical conduct of the anti-malarial drug trials is the lack of informed consent by participants in both trials. The Inquiry has found that participants in both trials were appropriately informed by the AMI medical investigators, in a manner comprehensible to them, of the potential side effects of both the experimental drug, tafenoquine, and the registered drug, mefloquine; and understood that participation in the trial was voluntary without detriment to deployment or future career and they could withdraw any time during the trial. In respect of mefloquine side effects, the information provided was consistent with the 1998 Lariam (mefloquine) Consumer Medicine Information leaflet which lists the potential side effects of the drug and which is ordinarily passed to the user when the drug is prescribed.

419. The Inquiry is satisfied that in both trials AMI investigators did not act unethically or unreasonably by not disclosing to trial participants ‘mefloquine neurotoxicity’ (permanent brain or CNS injury) as a foreseeable likely side effect of taking mefloquine (which the AMI investigators and Defence health authorities did not accept as a possible side effect of taking mefloquine). The AMI medical briefings and trial consent forms were consistent with the 1998 Lariam Product and Consumer Medicine Information, which did not recognise and include ‘mefloquine neurotoxicity’ as a possible side effect of mefloquine use.

420. **Complaint from 4 RAR soldier.** After examining a subsequent complaint made in May 2016 by a former 4 RAR soldier, the Inquiry is satisfied that his consent to participate in the 4 RAR mefloquine drug trial was not, as he claimed, unreasonably and unfairly obtained. The trial process was conducted in an appropriate manner to ensure the soldier’s decision to participate (by signing the consent form), and to continue to participate after being prescribed mefloquine, was based on informed consent. That the soldier may have received the consent form in the dark and
could not read it, or chose not to read it and sign it anyway, had no impact on the information, concerning the side effects of mefloquine and the voluntary nature of the trial, he would have already received at an earlier medical briefing.

INFORMED CONSENT: VOLUNTARY PARTICIPATION IN TRIALS (DIRECTION 2)

421. The second alleged breach of the NHMRC guidelines concerning informed consent is that participation in the trials; in particular the 1 RAR trial was not voluntary.

Voluntary participation: 1 RAR trial

422. During the pre-deployment phase in mid 2000, the then CO 1 RAR, LTCOL Caligari, is claimed to have addressed the battalion and said words to the effect that soldiers who did not volunteer and participate in the tafenoquine anti-malarial drug trial would be excluded from deployment. The now-LTGEN Caligari (Retd) adamantly denies the allegation.

423. It is accepted by most witnesses that CO 1 RAR was focused on taking all necessary precautions to prevent 1 RAR soldiers contracting malaria. Consequently, he addressed the battalion in detail about the malaria issue, and in doing so actively sought to encourage participation in the voluntary drug trial, which he fully supported, was participating in, and believed would assist in preventing malaria in the unit. The evidence of the six witnesses identified by MAJ McCarthy, with slight variations, was that CO 1 RAR said words to the effect if soldiers did not participate in the voluntary trial, they would not deploy. All six witnesses 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. Furthermore, they all believe they did not misinterpret encouragement, or an expectation by the CO of participation, as a direction or threat that non-participation would result in non-deployment. However, the witnesses’ overall memories of events 16 years ago surrounding the anti-malarial drug trial, which was conducted during a busy pre-deployment phase, are generally poor and lack detail.

424. Evidence received from eight witnesses who held key command appointments within the battalion was that the trial was voluntary, and none of those eight 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. Two of the former company commanders had a good memory of the pre-deployment phase, including the medical briefings and the CO addressing the battalion. Their evidence corroborated LTGEN Caligari’s account in most aspects. They indicated that had they heard the words, to the effect if soldiers did not participate in the voluntary trial they would not deploy, the company commanders would have remembered them and definitely raised the matter with the CO.

425. The Inquiry is satisfied that CO 1 RAR did not need to threaten soldiers with non-deployment if they did not participate in the trial, as by strongly supporting the trial and telling them that he was volunteering, he would achieve his aim of ensuring sufficient participation in the trial by 1 RAR soldiers. 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. This likely led to an expectation by command and soldiers themselves that everyone would participate in the trial. In any event, it is apparent that it did not occur to most soldiers not to participate, and a
decision whether or not to participate in the trial was not a significant issue to them; rather, that decision was just another tick in the pre-deployment list of things to be completed.

426. No witness could remember the actual words CO 1 RAR is alleged to have said, but rather the 'effect' of what he said. Given the intensity of a pre-deployment environment, it is possible some of those present for the CO’s address, including the six witnesses identified by MAJ McCarthy, 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; or alternatively, as an expectation that they were required to participate as part of the deployment.

427. In summary, the Inquiry finds there is differing but credible evidence provided by the six witnesses identified by MAJ McCarthy, and the former command group officers and LTGEN Caligari concerning voluntary participation in the trial. Accordingly, the Inquiry is not satisfied by the sufficiency and quality of the evidence to make an adverse finding that the CO used the alleged words (or a similar threat or direction) to the effect that participation in the trial was required in order to deploy to East Timor. Hence, MAJ McCarthy’s allegation is not substantiated.

Voluntary participation: 2 RAR and 4 RAR trials

428. The Inquiry finds that participation in the subsequent 2 RAR and 4 RAR anti-malarial drug trials involving mefloquine was voluntary, soldiers were aware that it was, and they made informed decisions whether to participate or not. There is no credible evidence of any coercion of soldiers by the CO or others in command to participate in the trials. While there may have been rumours of coercion and encouragement to participate in the 2 RAR trial, this did not invalidate the informed consent process.

Participation in future trials

429. The Inquiry is satisfied the voluntary nature of the anti-malarial drug trials was clearly reinforced during the medical briefings and consent process, and that consent was both informed and voluntary in compliance with the NHMRC guidelines. However, the ready acceptance by soldiers of advice or encouragement provided to them by military persons in authority, combined with a potential belief that participation in the trial was expected, is an issue worthy of further consideration in the conduct of any future medical trials, particularly in the context of a pre-deployment for an overseas operation.

THREATS OF DISCIPLINARY ACTION AND INTIMIDATION (DIRECTION 3)

430. The Inquiry also examined three complaints that MAJ McCarthy was allegedly threatened with disciplinary (or administrative) action and intimidated for publicly expressing concern for individuals allegedly affected by mefloquine, and attempting to highlight the mefloquine issue to the Senate Inquiry and to persons in the Defence hierarchy, including The three allegations are not substantiated.
First complaint

431. MAJ McCarthy's first complaint is that as a result of a telephone conversation and email exchange with [redacted] concerning mefloquine, he was subsequently threatened in March 2015 with disciplinary action for seeking appropriate care for ADF personnel and veterans affected by alleged mefloquine neurotoxicity. The Inquiry ascertained that on 26 March 2015, MAJ McCarthy was formally counselled by his CO about Defence policy on public comment, dissemination of official information and use of social media, and a Record of Conversation made. The formal counselling was instigated by AHQ, not [redacted], as a result of the inappropriate comments made on Facebook by MAJ McCarthy concerning and the Surgeon-General ADF. During that counselling MAJ McCarthy was advised that failure to comply with Defence policy may result in discipline or administrative action being taken against him.

432. Accordingly, the Inquiry finds that MAJ McCarthy was not threatened with disciplinary action for publicly expressing concern for individuals allegedly affected by mefloquine as he claims; rather he was informed he could continue to use Facebook to pursue his interest about raising awareness about the risks associated with mefloquine, as long as he did not post information that could be considered prejudicial to his position as an officer in the Army.

Second complaint

433. MAJ McCarthy's second complaint is an allegation of intimidation by VCDF and his CO comprising a public attack on his credibility (by VCDF) and a threat of disciplinary action (by his CO), which he asserts were both orchestrated to dissuade him from giving evidence about the ADF's use of mefloquine at a Senate Inquiry into the mental health of ADF personnel. The allegation arises out of The Australian newspaper article of 24 August 2015 quoting MAJ McCarthy from his Senate submission, and VCDF's 'on the record' reply that day, which included a statement that many of the claims in the article were unsubstantiated, particularly those concerning the unethical nature of the East Timor anti-malarial drug trials involving mefloquine.

434. The VCDF media response of 24 August 2015 did not focus on MAJ McCarthy and did not personally attack his credibility, but sought to address and to correct claims and allegations in The Australian newspaper article Defence considered were inaccurate and unsubstantiated. The response was not intended to intimidate MAJ McCarthy, and his belief the response was a direct attack on his credibility is not a reasonable inference to be drawn from the evidence.

435. On the same day MAJ McCarthy was asked by his CO whether he had been involved in writing The Australian newspaper article about the conduct of unethical anti-malarial drug trials by the ADF. MAJ McCarthy was reminded by his CO of their previous discussions about speaking to the media on the mefloquine issue. At the time both officers were unaware of VCDF's 'on the record' response to the newspaper article. The CO accepted MAJ McCarthy's explanation that he had not spoken to the media and the newspaper article was quoting from his written submission to the Senate Inquiry. When MAJ McCarthy later became aware of VCDF's response, he formed the view the CO's reminder was a command directed threat of disciplinary action and part of an
orchestrated act of intimidation against him because he was about to appear before the Senate Inquiry to give evidence about the ADF’s use of mefloquine. The Inquiry finds the CO was acting of his own volition, and not at the direction of command. The reminder to MAJ McCarthy about the limitations on speaking to the media was not an improper threat of disciplinary action.

Third complaint

436. The third complaint arose during the conduct of the IGADF Inquiry. On 03 February 2016, MAJ McCarthy was counselled by his CO about tweeting, in late December 2015 and January 2016, inappropriate and derogatory comments about the former Chief of Army and the Prime Minister on a twitter account, titled Stuart McCarthy@StuartMcCarthy. The subsequent direction by COFS HQ 2 Div for MAJ McCarthy to arrange an appointment with his CO for a second interview about the tweeting was legitimate, and was not intimidation or harassment as claimed by MAJ McCarthy, because the CO had previously discussed the matter with him.

437. Subsequently, a disciplinary investigation under the DFDA was conducted into MAJ McCarthy’s alleged breach of Defence public comment and social media policy for posting the inappropriate and derogatory comments. Ultimately DFDA action was not proceeded with. The instigation of the disciplinary investigation was appropriate (fair and reasonable), particularly given MAJ McCarthy’s previous formal counselling on similar matters. The conduct of the investigation was not an abuse of power to harass or intimidate MAJ McCarthy for publicly commenting on the effects of mefloquine on Defence members.

ALLEGED DECEPTIVE AND MISLEADING CONDUCT BY COL BRENNAN (DIRECTION 4)

438. MAJ McCarthy’s final and more general complaint concerns the actions of COL (now-BRIG) Brennan, a senior medical officer at JHC, who was an investigator in the 1 RAR tafenoquine trial in 2000. He complains that then-COL Brennan has failed on at least three occasions to disclose what MAJ McCarthy alleges were the known permanent neurotoxic adverse effects of mefloquine to appropriate authorities, or in published research papers. MAJ McCarthy believes these actions are tantamount to fraud (deceptive or misleading conduct) or negligence, by then-COL Brennan.

439. The Inquiry finds there is no evidence that during the conduct of the 2000 to 2002 AMI anti-malarial drug trials, COL Brennan became aware of, or otherwise failed to disclose, any neurotoxic adverse side effects of mefloquine to appropriate authorities or his chain of command. Subsequently, COL Brennan did not engage in deceptive or misleading conduct to cover up or hide the true impact from senior ADF officers, or the wider ADF and veteran community, of what MAJ McCarthy asserted were the known neurotoxic side effects of mefloquine use (mefloquine neurotoxicity). The Inquiry finds there was no evidence that COL Brennan deliberately or negligently failed to appropriately disclose evidence of mefloquine neurotoxicity in published research papers.

440. MAJ McCarthy’s additional complaint that then-LTCOL Brennan had a conflict of interest when he assisted an investigator in the preliminary stages of the 1 RAR tafenoquine trial, when he was the Senior Medical Officer at Headquarters 3rd Brigade, is not substantiated. The role of the Senior Medical Officer at Headquarters 3rd Brigade is to provide advice to the Brigade Commander.
The Inquiry finds that there was no conflict of interest in then-LTCOL Brennan’s assisting as an investigator in the trial. The reasons for this include that then-LTCOL Brennan was not a Principal Investigator but merely assisted in the conduct of the early stages of the trial. Then-LTCOL Brennan’s assistance was declared to the Brigade Commander who allowed it. Furthermore, the conduct of the trial was not a matter for the Brigade Commander’s decision. Participation in the trial was an individual decision on the part of every soldier. The assertion that then-LTCOL Brennan was not in a position to give impartial advice to CO 1 RAR is also not relevant. Had CO 1 RAR required medical advice about any aspect of the trial, that advice would not have been provided by then-LTCOL Brennan but by CO 1 RAR’s own Regimental Medical Officer. In these circumstances, no issue of conflict of interest arose.

CONCLUSION

441. In conclusion, the Inquiry finds that MAJ Mccarthy’s complaints about the conduct of the 2000 to 2002 anti-malarial drug trials are unsubstantiated. The trials were conducted ethically and in compliance with NHMRC National Guidelines, with special care taken to allow for the hierarchical 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. MAJ McCarthy was not threatened with disciplinary action, or intimidated, by VCDF and senior officers, for expressing concern for individuals allegedly affected by mefloquine use. COL (now-BRIG) Brennan (and by implication Defence) has not engaged in deceptive or misleading conduct to cover up what MAJ McCarthy asserts are the known neurotoxic side effects of mefloquine use (mefloquine neurotoxicity) on ADF personnel.

J M Gaynor, CSC
Brigadier
Acting Inspector-General of the Australian Defence Force

♀♀ September 2016